SCHEDULING STATUS: S3

1. NAME OF MEDICINE
PIXICAM® 20 (dispersible tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each dispersible tablet contains piroxicam 20 mg.
Contains sugar (lactose monohydrate 169 mg).
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Dispersible tablets.
Round, biconvex with a score notch, uniform white to light yellow tablet 9 mm x 4 mm.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
PIXICAM 20 is used in musculoskeletal and joint disorders such as ankylosing spondylitis, osteoarthritis, and rheumatoid arthritis. In addition, PIXICAM 20 may be used in acute musculoskeletal conditions and acute gout.
Due to its safety profile (see 4.2 *Posology and method of administration*, 4.3 *Contraindications* and 4.4 *Special warnings and precautions for use*), PIXICAM 20 is not a first line option should a NSAID be indicated. The decision to prescribe PIXICAM 20 should be based on an assessment of the individual patient's overall risks (see 4.3 *Contraindications* and 4.4 *Special warnings and precautions for use*).

4.2 Posology and method of administration
The prescription of PIXICAM 20 should be initiated by physicians with experience in the diagnostic evaluation and treatment of patients with inflammatory or degenerative rheumatic diseases.

The recommended starting daily dose is 20 mg.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see 4.4 *Special warnings and precautions for use*). The benefit and tolerability of treatment should be reviewed within 14 days. If continued treatment is considered necessary, this should be accompanied by frequent review.
Given that PIXICAM 20 has been shown to be associated with an increased risk of gastrointestinal complications, the possible need for combination therapy with gastroprotective agents (e.g., misoprostol or proton pump inhibitors) should be carefully considered, in particular for elderly patients.

Ankylosing spondylitis, osteoarthritis and rheumatoid arthritis:
The usual dose is 20 mg daily, although doses of 10 – 30 mg daily have been used. Long-term administration of 30 mg or more daily has been associated with an increase in gastrointestinal side effects. Because of the long half-life, steady-state concentrations are not reached for 7 – 12 days but will occur sooner if a loading dose is given.

Acute musculoskeletal conditions:
40 mg daily for 2 days (in single or divided doses), followed by 20 mg daily for 1 – 2 weeks.

Acute gout:
40 mg daily (in single or divided doses), for 4 – 6 days. PIXICAM 20 (piroxicam) is not indicated for long-term management of gout.

Method of administration
For oral administration.
The tablets may be swallowed whole with adequate water or may be dispersed in a small quantity of water, in a glass and the solution then swallowed.

4.3 Contraindications
- Hypersensitivity to piroxicam, other oxicam compounds or to any of the excipients (see Section 6.1 *List of excipients*)
- Haemopoietic disorders
- Patients in whom acetylsalicylic acid or other non-steroidal anti-inflammatory medicines induce symptoms of asthma, rhinitis, angioedema or urticaria
- History of gastrointestinal ulceration, bleeding or perforation
- Patient history of gastrointestinal disorders that predispose to bleeding disorders such as ulcerative colitis, Crohn's disease, gastrointestinal cancers or diverticulitis
- Patients with active peptic ulcer, inflammatory gastrointestinal disorder or gastrointestinal bleeding
- Concomitant use with other NSAIDs, including COX-2 selective NSAIDs and acetylsalicylic acid at analgesic doses
- Concomitant use with coumarin-type anticoagulants
- History of previous serious allergic drug reaction of any type, especially cutaneous reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis
- Previous skin reaction (regardless to severity) to piroxicam, other NSAIDs and other medications
- Cerebrovascular or other active haemorrhages
- General haemorrhagic diathesis
- Moderate or severe heart failure
- Severe renal or hepatic insufficiency
- Treatment of perioperative pain following bypass surgery (CABG)
- During the last trimester of pregnancy
- Children and adolescents under the age of 15 years.

4.4 Special warnings and precautions for use
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see 4.2 *Posology and method of administration* and GI and cardiovascular risks below).

The clinical benefit and tolerability should be re-evaluated periodically, and treatment should be immediately discontinued at the first appearance of cutaneous reactions or relevant gastrointestinal events.

Elderly patients:
The elderly has an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation (PUBs) which may be fatal (see 4.2 *Posology and method of administration*).

Gastrointestinal (GI) bleeding, ulceration and perforation:
NSAIDs, including PIXICAM 20, can cause serious gastrointestinal events including bleeding, ulceration and perforation of the stomach, small intestine or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs.

NSAID exposures of both short and long duration have an increased risk of serious GI events.

Epidemiological evidence suggests that PIXICAM 20 may be associated with a high risk of serious gastrointestinal toxicity, relative to other NSAIDs (see 4.1 *Therapeutic Indications* and 4.2 *Contraindications*).

Patients with significant risk factors for serious GI events should be treated with PIXICAM 20 only after careful consideration (see 4.2 *Contraindications*).

The possible need for combination therapy with gastroprotective agents (e.g., misoprostol or proton pump inhibitors) should be carefully considered (see 4.2 *Posology and method of administration*).

Serious GI complications
Identification of at-risk subjects
The risk for developing serious GI complications increases with age. Age over 70 years is associated with a high risk of complications. Administration to patients older than 80 years should be avoided.

Patients taking concomitant oral corticosteroids, selective serotonin reuptake inhibitors (SSRIs) or anti-platelet agents such as low-dose acetylsalicylic acid are at increased risk of serious GI complications (see below and section 4.5). As with other NSAIDs, the use of PIXICAM 20 in combination with protective agents (e.g., misoprostol or proton pump inhibitors) must be considered for these at-risk patients.

Patients and physicians should remain alerted for signs and symptoms of GI ulceration and/or bleeding during PIXICAM 20 treatment. Patients should be asked to report any new or unusual abdominal symptoms during treatment. If a gastrointestinal complication is suspected during treatment, PIXICAM 20 should be discontinued immediately, and additional clinical evaluation and treatment should be considered.

Cardiovascular and cerebrovascular effects
Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy. PIXICAM 20 is contraindicated in patients with moderate to severe heart failure (see Section 4.3 *Contraindications*).

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and long-term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for PIXICAM 20.

Patients with uncontrolled hypertension, mild congestive heart failure, established ischaemic heart disease, and/or cerebrovascular disease should only be treated with PIXICAM 20 after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular disease (e.g., hypertension, hyperlipidaemia, diabetes mellitus, smoking).

Skin reactions
Life-threatening cutaneous reactions, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the use of PIXICAM 20.
Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment.
If symptoms or signs of SJS or TEN (e.g., progressive skin rash often with blisters or mucosal lesions) are present, PIXICAM 20 treatment should be discontinued.
The best results in managing SJS and TEN come from early diagnosis and immediate discontinuation of any suspect medicine. Early withdrawal is associated with a better prognosis.
If the patient has developed SJS or TEN with the use of PIXICAM 20, PIXICAM 20 must not be re-started in this patient at any time.

There have been reports of fixed drug eruptions (FDE) with PIXICAM 20. Do not reintroduce PIXICAM 20 in patients with a history of piroxicam-related FDE. There is potential for cross-reactivity with other oxicams. Piroxicam should be discontinued at the first appearance of a skin rash, mucosal lesions, or any other sign of hypersensitivity.

Inducible porphyria
PIXICAM 20 should be used only after strict assessment of the benefit-risk ratio in inducible porphyria.

Renal effects
In rare cases, NSAIDs may cause interstitial nephritis, glomerulonephritis, papillary necrosis and the nephrotic syndrome. Such agents inhibit the synthesis of renal prostaglandins which play a supportive role in the maintenance of renal perfusion in patients whose renal blood flow and blood volume are decreased. In these patients, administration of a non-steroidal anti-inflammatory medicinal product may precipitate overt renal insufficiency, which is typically followed by recovery to pre-treatment state upon discontinuation of non-steroidal anti-inflammatory therapy.

Patients at greatest risk of such a reaction are those with chronic cardiac insufficiency, liver cirrhosis, nephrotic syndrome or overt renal disease, and patients after recent major surgery. Therefore, such patients should be carefully monitored whilst receiving nonsteroidal anti-inflammatory therapy.

Hepatic effects
PIXICAM 20 may induce hepatitis and jaundice with fatal outcome. Though rarely, treatment should be discontinued if abnormal liver values persist or deteriorate, or if clinical symptoms suggesting hepatopathy or systemic symptoms (e.g., eosinophilia, exanthema) occur.

Eyes
Because of reports of adverse eye findings with non-steroidal anti-inflammatory medicinal products, it is recommended that patients who develop visual complaints during treatment with PIXICAM 20 have ophthalmic evaluation.

Poor metabolisers of CYP2C9 substrates
Patients who are known or suspected to be poor CYP2C9 metabolisers based on previous history/experience with other CYP2C9 substrates should be administered PIXICAM 20 with caution as they may have abnormally high plasma levels due to reduced metabolic clearance.

General
Patients suffering from hay fever, nasal polyps or chronic obstructive respiratory diseases as well as patients with hypersensitivity to other non-steroidal antiphlogistics/analgesics may use PIXICAM 20 only while heeding certain precautionary measures and under direct medical monitoring, as they are at higher risk of allergic reactions. These can manifest themselves as asthmatic attacks (so-called analgesic asthma), Quincke's oedema or urticaria.

Special caution is also required in patients with allergic reactions to other substances, as they are also at elevated risk of experiencing hypersensitivity reactions when using PIXICAM 20.

Like other NSAIDs, PIXICAM 20 can inhibit thrombocyte aggregation and prolong bleeding time. This has to be considered if evaluating bleeding time.

Longer-term administration of PIXICAM 20 requires regular monitoring of the blood picture (haemoglobin, haematocrit), blood coagulation, as well as hepatic and renal function.

Further notes
During longer-term high-dosed, improper use of analgesics, headache may occur which must not be treated with elevated doses of the medicinal product.

Quite in general, habitual intake of analgesics, particularly in combination with several analgesic agents, may lead to permanent renal damage with the risk of renal failure (analgesic nephropathy).

Laboratory tests
It is recommended when administering PIXICAM 20 to patients with a history of hepatic or renal disease to periodically check hepatic or renal function. Regular monitoring of these functions during treatment is particularly indicated in elderly patients who often exhibit progressive deterioration of these functions with age.

Lactose intolerance
PIXICAM 20 contains lactose. Patients with the rare hereditary conditions of galactose intolerance, e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance, should not take PIXICAM 20.

4.5 Interactions with other medicines and other forms of interaction
Aspirin and other NSAIDS
As with other NSAIDs, the use of PIXICAM 20 together with acetylsalicylic acid or concomitant use with other NSAIDs, including other piroxicam formulations, must be avoided, since data are inadequate to show that such combinations produce greater improvement than that achieved with PIXICAM 20 alone; moreover, the potential for adverse reactions is enhanced (see 4.4 *Special warnings and precautions for use*). Human studies have shown that concomitant use of PIXICAM 20 and acetylsalicylic acid reduces the plasma PIXICAM 20 concentration to about 80 % of the usual value.

Corticosteroids
Concomitant administration of PIXICAM 20 and glucocorticoids increases the risk of gastrointestinal ulceration or bleeding (see 4.4 *Special warnings and precautions for use* and 4.8 *Undesirable effects*).

Probenecid
Concurrent intake of probenecid may result in delayed excretion of PIXICAM 20.

Cimetidine
Concurrent intake of cimetidine may result in delayed excretion of PIXICAM 20 and thus in an enhancement of its adverse effects.

Phenytoin, lithium
Co-administration of PIXICAM 20 and phenytoin or lithium may increase the serum levels of these medicinal products.
If PIXICAM 20 and lithium preparations are administered concurrently, monitoring of lithium concentrations in blood is necessary and dose adaption recommended if PIXICAM 20 treatment is initiated, adapted, or discontinued.

Potassium-sparing diuretics, potassium-containing medicinal products
Co-administration of PIXICAM 20 and potassium-sparing diuretics as well as potassium-containing medicinal products may lead to an increased potassium level in serum.

Diuretics, antihypertensives
PIXICAM 20 can attenuate the effect of diuretics and antihypertensives and renal damage may occur (sufficient fluid intake is necessary, and blood pressure should be monitored).
Patients should be adequately hydrated, and the need to monitor the renal function should be assessed at the beginning of the concomitant treatment and periodically thereafter.

Methotrexate
Administration of PIXICAM 20 prior to or following administration of methotrexate may lead to increased methotrexate serum concentrations due to reduced excretion of methotrexate and subsequently to increased adverse effects. The combination should be avoided.

Anticoagulants
NSAIDs, including PIXICAM 20 may enhance the effects of anticoagulants, such as warfarin. Therefore, the use of PIXICAM 20 with concomitant anticoagulants such as warfarin is contraindicated (see 4.3 *Contraindications*).

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs)
Increased risk of gastrointestinal bleeding (see 4.4 *Special warnings and precautions for use*).

Ciclosporin and tacrolimus
Co-administration of PIXICAM 20 and ciclosporin may increase the risk of gastrointestinal, renal or hepatic damage. The combination should be avoided and the PIXICAM 20 dose reduced. Renal and hepatic function should be monitored.
There is a possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Highly protein bound medicinal products
PIXICAM 20 is highly protein bound and might displace other protein-bound medicinal products, thereby increasing their (adverse) effects.

Cardiac glycosides
NSAIDs are reported to increase blood concentrations of these medicinal products. However, this was not observed in a study with PIXICAM 20.

Cholestyramine
Cholestyramine may increase PIXICAM 20 elimination.

Oral antidiabetics
Concomitant administration may lead to fluctuations of blood glucose levels. Therefore, blood glucose levels should be monitored intensively.

Quinolone antibiotics
When PIXICAM 20 is given in combination with quinolone antibiotics, there is a possible increased risk of convulsions.

Mifepristone
NSAIDs, including PIXICAM 20, may interfere with mifepristone-mediated termination of pregnancy.

4.6 Fertility, pregnancy and lactation
Fertility:
Based on the mechanism of action of NSAIDs, the use of PIXICAM 20 may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women. Consider withdrawal of NSAIDs, including PIXICAM 20, in women who have difficulties conceiving or who are undergoing investigation of infertility.

Pregnancy:
Safety during pregnancy and lactation has not yet been established. Use of PIXICAM 20 is contraindicated in the last trimester of pregnancy (see Section 4.3 *Contraindications*). Regular use of non-steroidal anti-inflammatory drugs such as PIXICAM 20 during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus *in utero*, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed, and its duration increased.

Lactation:
Piroxicam is distributed into breast milk. Since clinical safety has not been established, PIXICAM 20 is not recommended for use in nursing mothers.

4.7 Effects on the ability to drive or use machinery
The effects of PIXICAM 20 on the ability to drive and use machines have not been investigated. If central nervous side effects such as fatigue, dizziness, drowsiness, and vertigo occur during administration of PIXICAM 20 at higher dose, the ability to drive and/or to use machines can be impaired in the individual case. This applies to a greater extent in combination with alcohol. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects
The evaluation of undesirable effects is based on the following information on frequency:
Frequent: ≥ 1/10; ≥ 1/100 up to < 1/10
Less frequent: ≥ 1/1 000 up to < 1/100; ≥ 1/10 000 up to < 1/1 000; < 1/10 000
Not known: cannot be estimated from the available data

Blood and lymphatic system disorders:
Frequent: Anaemia, eosinophilia, leukopenia, thrombocytopenia
Not known: Aplastic anaemia, haemolytic anaemia

Immune System disorders:
Not known: Anaphylaxis, serum sickness

Metabolism and nutrition disorders:
Frequent: Anorexia, hyperglycaemia
Less frequent: Hypoglycaemia
Not known: Fluid retention

Psychiatric disorders:
Not known: Depression, dream abnormalities, hallucinations, insomnia, mental confusion, mood alterations, nervousness

Nervous system disorders:
Frequent: Dizziness, headache, somnolence, vertigo
Not known: Paraesthesia

Eye disorders:
Less frequent: Blurred vision
Not known: Eye irritations, swollen eyes

Ear and labyrinth disorders:
Frequent: Tinnitus
Not known: Hearing impairment

Cardiac disorders:
Less frequent: Palpitations.
Not known: Cardiac failure**

Vascular disorders:
Not known: Vasculitis, hypertension**, arterial thrombotic events**

Respiratory, thoracic and mediastinal disorders:
Not known: Bronchospasm, dyspnoea, epistaxis

Gastrointestinal disorders*:
Frequent: Abdominal discomfort, abdominal pain, constipation, diarrhoea, epigastric distress, flatulence, nausea, vomiting, indigestion
Less frequent: Stomatitis
Not known: Gastritis, gastrointestinal bleeding (including melaena and haematemesis), pancreatitis, perforation, ulceration, exacerbation of colitis and Crohn's disease, ulcerative stomatitis

Hepatobiliary disorders:
Not known: Fatal hepatitis*** or jaundice***

Skin and subcutaneous tissue disorders:
Frequent: Pruritis, skin rash
Less frequent: Severe cutaneous adverse reactions (SCARs), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) (see Section 4.4 *Special warnings and precautions for use)*
Not known: Alopecia, angioedema, dermatitis exfoliative, erythema multiforme, non-thrombocytopenic purpura (Henoch-Schoenlein), onycholysis, photoallergic reactions, urticaria, vesiculo-bullous reactions, fixed drug eruption (see Section 4.4 *Special warnings and precautions for use*)

Renal and urinary disorders:
Not known: Nephrotic syndrome, glomerulonephritis, interstitial nephritis****, renal failure

Reproductive system and breast disorders:
Not known: Female fertility decreased

General disorders and administration site conditions:
Frequent: Oedema (mainly of the ankle)**
Not known: Malaise

Investigations:
Frequent: Reversible elevations of BUN (blood urea nitrogen), increased serum transaminase levels***, weight increase
Less frequent: Reversible elevations of creatinine
Not known: Positive ANA, weight increase, decreases in haemoglobin and haematocrit unassociated with obvious gastrointestinal bleeding

*The most commonly observed adverse events are gastrointestinal in nature.
**Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and with long-term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see 4.4 *Special warnings and precautions for use*).
***Changes of several liver function parameters have been observed. As with most other non-steroidal anti-inflammatory medicinal products, increased serum transaminase levels during treatment with PIXICAM 20 may occur in some patients (see 4.4 *Special warnings and precautions for use*).
****In rare cases, NSAIDs may cause acute interstitial nephritis. Such agents inhibit the synthesis of renal prostaglandins which play a supportive role in the maintenance of renal perfusion in patients whose renal blood flow and blood volume are decreased, such as in severe congestive heart failure, dehydration, nephrotic syndrome, cirrhosis of the liver, or pre-existing renal disease.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Symptoms of overdose
The main symptoms are gastrointestinal disturbances, such as nausea, vomiting, abdominal pain, dizziness, headache, confusion, tinnitus, hyperventilation including respiratory alkalosis. Furthermore, sedation, hyperpyrexia, respiratory and metabolic acidosis, toxic circulatory failure, renal impairment (haematuria, proteinuria, acute renal failure) as well as hepatic impairment (hypoprothrombinaemia); cerebral and pulmonary oedema, enhanced convulsibility and coma. In children, hypoglycaemia is possible.

Therapeutic measures in overdose
No specific antidote exists. Intensive medical supervision may be necessary. The long half-life of PIXICAM 20 is to be considered.

Based on animal tests, administration of antacids and activated charcoal is assumed to possibly accelerate the excretion of PIXICAM 20.

Studies indicate that administration of activated charcoal may result in reduced absorption and reabsorption of PIXICAM 20, thus reducing the total amount of active drug available.

According to current data, haemodialysis is not suited – on account of the high protein binding of PIXICAM 20 – to eliminate PIXICAM 20 from the blood.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological class
A 3.1 Antirheumatics (anti-inflammatory agents).
ATC Classification
M01AC01 - oxicams
Anti-inflammatory and antirheumatic products, nonsteroids.
Piroxicam has analgesic, anti-inflammatory and anti-pyretic properties.

5.2 Pharmacokinetic properties:
Piroxicam is well absorbed from the gastrointestinal tract: peak plasma concentrations are reached 3 to 5 hours after an oral dose. It is metabolised in the liver by hydroxylation and conjugation with glucuronic acid and is excreted predominantly in the urine with smaller amounts in the faeces. Enterohepatic recycling occurs. Less than 5 % of the dose is excreted unchanged. Piroxicam is extensively bound to plasma proteins (about 99 %) and has a long plasma half-life of approximately 50 hours.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Colloidal silica anhydrous, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium dodecyl sulphate.

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
36 months when stored at or below 25 °C. Protect from light.

6.4 Special precautions for storage
This medicine does not require any special storage conditions.

6.5 Nature and contents of container
PIXICAM 20 is available in packs of 30 and 100 dispersible tablets.
Supplied in white HDPE securitainers or polypropylene foil blisters.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Kiara Health (Pty) Ltd
72 Steel Road, Spartan
Kempton Park, 1619
South Africa

8. REGISTRATION NUMBER
29/3.1/0752

9. DATE OF FIRST AUTHORISATION
09 April 1997

10. DATE OF REVISION OF THE TEXT
08 May 2023

Additional countries registration details:

Country	Product name	Scheduling status (or Category of distribution)	Registration number
Namibia	PIXICAM® 20	NS2	04/3.1/1348
Botswana	PIXICAM® 20	S2	BOT1703203
Mauritius	PIXICAM® 20		R2930/02/14
Zambia	PIXICAM® 20		039/045

Name and address of manufacturer:
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39179 Barleben, Germany

Kiara Health (Pty) Ltd
72 Steel Road,
Spartan, Kempton Park
1619, South Africa

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PIXICAM® 20 (dispersible tablets)
Piroxicam 20 mg
Contains sugar (169 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking PIXICAM 20
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- PIXICAM 20 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet?

1. What PIXICAM 20 is and what it is used for
2. What you need to know before you take PIXICAM 20
3. How to take PIXICAM 20
4. Possible side effects
5. How to store PIXICAM 20
6. Contents of the pack and other information

1. What PIXICAM 20 is and what is it used for
Each dispersible tablet contains piroxicam 20 mg.
PIXICAM 20 is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). PIXICAM 20 is used to relieve some symptoms caused by osteoarthritis (arthrosis, degenerative joint disease), rheumatoid arthritis and ankylosing spondylitis (rheumatism of the spine), such as swelling, stiffness and joint pain. This medicine does not cure arthritis and will help you only as long as you continue to take it.

Your doctor will only prescribe PIXICAM 20 to you when you have had unsatisfactory relief of symptoms with other NSAIDs.

2. What you need to know before you take PIXICAM 20
Do not take PIXICAM 20
- If you are hypersensitive (allergic) to piroxicam, similar medicines called oxycams, or any of the other ingredients in PIXICAM 20. (Please see **What PIXICAM 20 contains.**)
- If you have blood formation disorders.
- If you have ever had an allergy to acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs (NSAIDs) such as diclofenac or ibuprofen. Allergic reactions can include wheezing (asthma attacks), itchy runny nose, rashes or swelling of the skin.
- If you have previously had or currently have a stomach or intestinal ulcer, bleeding or perforation.
- If you have or have previously had disorders of the stomach or intestines that predispose to bleeding disorders such as ulcerative colitis, Crohn's disease, gastrointestinal cancers, or diverticulitis (inflamed or infected pouches/pockets in the colon).
- If you are taking other NSAIDs such as ibuprofen, including COX-2 selective NSAIDs such as celecoxib, or acetylsalicylic acid (aspirin), a substance present in many medicines used to relieve pain and lower fever.
- If you are taking anticoagulants, such as warfarin, to prevent blood clots.
- If you previously had a serious allergic reaction of any type to any medicine, especially skin reactions such as exfoliative dermatitis (intense reddening of skin, with skin peeling off in scales or layers), Stevens-Johnson syndrome (symptoms are a rash, blistering or peeling of the skin, mouth, eyes or genitals) or toxic epidermal necrolysis (a disease with blistering and peeling of the top layer of skin).
- If you previously had a skin reaction (regardless of severity) to piroxicam, other NSAIDs and other medications.
- If you have bleeding in your brain or other active bleeding or tend to have bleeding in general.
- If you have moderate to severe heart failure.
- If you have severe liver or kidney dysfunction.
- If you have pain after a bypass surgery (CABG).
- If you are in the last three months of your pregnancy.
- If you are a child or adolescent (or you treat a child or adolescent) under the age of 15 years.

Warnings and precautions
Take special care/Special care should be taken with PIXICAM 20
- If you have heart problems or high blood pressure.
- If you suffer from mild to moderate liver disease. You should not take PIXICAM 20 if you have severe liver dysfunction (see **Do not take PIXICAM 20**).
- If you suffer from mild to moderate kidney disease. You should not take PIXICAM 20 if you have severe kidney dysfunction (see **Do not take PIXICAM 20**).
- If you have certain blood formation disorders called "porphyria".
- If you recently had major surgery.
- If you suffer from allergies, hay fever, asthma.

Your doctor may need to give you check-ups and will tell you how often you need to be checked during treatment with PIXICAM 20.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of PIXICAM 20, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, and genitals, and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.
The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of PIXICAM 20, you must not take it ever again (see **Do not take PIXICAM 20**).
Other examples of serious, and sometimes life-threatening, skin rashes include exfoliative dermatitis (extreme shedding of the top layers of the skin), and fixed drug eruption (where the rash will reappear with re-exposure to the same medicine). If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Medicines such as PIXICAM 20 may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If you have or think you might be at risk for these diseases (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker), if you have heart problems or previously had a stroke, you should discuss your treatment with your doctor or pharmacist.

You should stop taking PIXICAM 20 immediately and tell your doctor if you have any allergic reaction such as a skin rash, swelling of the face, wheezing or difficulty breathing.

Take special care with PIXICAM 20 as, like all NSAIDs, PIXICAM 20 can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration, and perforation.
You should stop taking PIXICAM 20 immediately and tell your doctor if you have stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements or vomiting blood.

Your doctor may prescribe PIXICAM 20 together with another medicine to protect your stomach and intestines from side effects (such as misoprostol or proton pump inhibitors), particularly if you are over 70 years old, or you are taking other medicines like corticosteroids (medicines given to treat a variety of conditions such as allergies and hormone imbalances), certain medicines for depression called selective serotonin reuptake inhibitors (SSRIs) or acetylsalicylic acid to help prevent heart attacks or stroke.

With long-term use of painkillers, headaches can occur which cannot be treated with higher doses of the pain medicines. Ask your doctor for advice if you often suffer from headaches despite taking medicines to treat pain.

The habitual intake of analgesics, particularly combinations of different analgesic medicines, may cause permanent kidney damage with the risk of kidney failure (analgesic nephropathy).

If you develop any visual complaints during treatment with PIXICAM 20, you should have an ophthalmic evaluation.

If you are taking PIXICAM 20 and are planning to become pregnant, especially if you have been experiencing difficulties conceiving or are undergoing investigation for infertility, talk to your doctor about possible withdrawal of PIXICAM 20 (see also **Pregnancy, breastfeeding, and fertility**).

Older people (over 70 years of age)
Older people have an increased risk of side effects to NSAIDs, especially bleeding in the stomach or intestines and perforation.
If you are over 70 years old, your doctor may wish to minimise the length of your treatment and to see you more often while you are taking PIXICAM 20. Your doctor may prescribe PIXICAM 20 together with another medicine to protect your stomach and intestines from potential side effects (see above).

You should not take this medicine if you are older than 80 years.

Children and adolescents
Do not use PIXICAM 20 if you are below 15 years of age.

Other medicines and PIXICAM 20
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The following medicines must not be taken with PIXICAM 20:
- Acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs for pain relief
- Anticoagulants such as warfarin to prevent blood clots.

Tell your doctor before you take PIXICAM 20, if you are taking any of the following medicines:
- Corticosteroids, medicines given to treat a variety of conditions such as allergies, inflammation, and hormone imbalances
- Antiplatelet agents such as low dose acetylsalicylic acid (aspirin) to help prevent blood clotting and heart attack or stroke

- Certain medicines used to treat heart conditions known as cardiac glycosides, such as digoxin
- Certain medicines for depression such as lithium or selective serotonin re-uptake inhibitors (SSRIs) (see **Warnings and precautions**)
- Antihypertensives to treat high blood pressure
- Methotrexate, which can be given to treat various conditions such as cancers, psoriasis and rheumatoid arthritis: the combination should be avoided
- Ciclosporin, used for prevention of transplant rejection, but also in the treatment of rheumatism
- Tacrolimus for the prevention of transplant rejection
- Diuretics ("water tablets") such as hydrochlorothiazide to treat high blood pressure or kidney problems
- Potassium-sparing medicines, such as certain diuretics
- Probenecid, a medicine for gout
- Cimetidine, a medicine to reduce gastric acid
- Phenytoin, a medicine for epilepsy
- Cholestyramine, a medicine to lower cholesterol levels
- Oral antidiabetics such as glimepiride or glipizide, medicines to control elevated blood sugar levels: you should check your blood sugar levels more often
- Quinolone antibiotics, such as ciprofloxacin, moxifloxacin, or levofloxacin, for the treatment of bacterial infections
- Mifepristone for termination of pregnancy.

PIXICAM 20 with food and drink and alcohol
Consumption of alcohol should be avoided while taking PIXICAM 20 as it may intensify possible side effects, especially those affecting the gastrointestinal tract and the central nervous system.

Pregnancy, breastfeeding, and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Do not take PIXICAM 20 if you are in the last three months of pregnancy, as it can harm your baby.
Safety during pregnancy and lactation has not yet been established.
The active substance piroxicam is excreted in small amounts into breast milk. Use of PIXICAM 20 during breastfeeding is not recommended.
NSAIDs, such as PIXICAM 20, may interfere with the release of eggs from the ovaries (see **Warnings and precautions**).

Driving and using machinery
PIXICAM 20 can cause some people to feel dizzy, drowsy, tired or have problems with their vision. If you are affected, do not drive or operate machinery.

PIXICAM 20 contains sugar (lactose monohydrate)
PIXICAM 20 contains an ingredient called lactose (milk sugar). If you have lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking PIXICAM 20.

3. How to take PIXICAM 20
Do not share medicines prescribed for you with any other person.

Always take PIXICAM 20 exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of PIXICAM 20. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms in order to minimise potential side effects. Under no circumstances should you change your dose without first speaking to your doctor.

The tablets may be swallowed whole with adequate water or may be dispersed in a small quantity of water in a glass and the solution then swallowed.

Adults
The usual daily dose of PIXICAM 20 is 20 milligrams taken as one single daily dose.
The maximum daily dose is 40 mg (in single or divided doses) for the short-term treatment of acute muscle and bone conditions or acute gout.

Older people
If you are older than 70 years, your doctor may prescribe a lower daily dose and reduce the duration of treatment.
Your doctor will tell you how long your treatment with PIXICAM 20 will last. If you have the impression that the effect of PIXICAM 20 is too strong or too weak, tell your doctor or pharmacist.

If you take more PIXICAM 20 than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose may include headache, dizziness, drowsiness, stomach pain, nausea, vomiting and hyperventilation.

If you forget to take PIXICAM 20
If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a missed dose.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
PIXICAM 20 can have side effects.
Not all side effects reported for PIXICAM 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

Tell your doctor immediately and stop taking PIXICAM 20 if you experience any of the following symptoms after taking this medicine:
- Any sign of bleeding in the stomach or intestines, such as passing black (tarry) or bloodstained bowel movements or vomiting blood
- Sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- Potentially life-threatening skin rashes including peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) or extensive peeling of the skin (toxic epidermal necrolysis) (see **Warnings and precautions**)
- Yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems.

Other side effects that may be experienced while taking this medicine are:
Frequent side effects:
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- High levels of a specific type of white blood cell (eosinophilia)
- Changes in white blood cell counts which may result in an increased risk of infection (leukopenia), or thrombocytopenia (reduction in blood platelets) which increases the risk of bleeding or bruising
- Loss of appetite
- Increase in blood sugar levels
- Dizziness, headache, sleepiness
- A feeling of dizziness or "spinning"
- Ringing in ears (tinnitus)
- Stomach pain/discomfort, constipation
- Diarrhoea, wind, feeling sick (nausea), vomiting, indigestion
- Itching, skin rash
- Swelling of the ankles, feet or fingers (oedema)
- Increase in liver enzymes
- Abnormal kidney function test results
- Weight increase.

Less-frequent side effects:
- Decreased/low blood sugar level which may cause faintness, hunger, sweating or jitteriness
- Blurred vision
- Feeling your heartbeat
- Sore mouth and/or lips.

Not known - frequency cannot be estimated from the available data
- Abnormalities in the blood such as severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia)
- Fluid retention
- Depression, dream abnormalities, hallucinations, difficulty in sleeping, mental confusion, mood alterations, nervousness
- Tingling or numbness (paraesthesia)
- Eye irritation, swollen eyes
- Difficulty hearing
- Heart failure with signs such as breathlessness, difficulty breathing when lying down, swelling of the feet or legs
- Inflammation of the blood vessels
- High blood pressure
- Forming of blood clots in blood vessels: heart attack (myocardial infarction) or stroke
- Difficulty in breathing or wheezing
- Nosebleed
- Inflammation of the stomach lining (gastritis)
- Inflammation of the pancreas (which may lead to severe pain in the upper abdomen or back)
- Gastrointestinal ulcers and/or perforation
- Worsening of colitis and Crohn's desease
- Ulcers in the mouth
- Inflammation of the liver (fatal hepatitis)
- Hair loss
- Allergic reaction involving purple spots on the skin, joint pain, abdominal pain and kidney dysfunction (Henoch-Schoenlein purpura)
- Loosening or splitting of fingernails
- Increased sensitivity of the skin to sunlight
- Kidney disease, kidney inflammation, kidney failure
- Decreased fertility of women
- Generally feeling unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PIXICAM 20

5. How to store PIXICAM 20
- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- Do not use the tablets after the expiry date printed on the container, blister, or label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information
What PIXICAM 20 contains
The active substance is piroxicam.
The other ingredients are colloidal silica anhydrous, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium dodecyl sulphate.

What PIXICAM 20 looks like and contents of the pack
PIXICAM 20 is a uniform white to light yellow round, biconvex 9 mm x 4 mm tablet with a score notch.
PIXICAM 20 is available in white HDPE securitainers or polypropylene foil blisters in packs of 30 and 100 dispersible tablets.

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PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS: S3

PIXICAM® 20 (oplosbare tablette)
Piroksikaam 20 mg
Bevat suiker (169 mg laktosemonohidraat per tablet)

Lees die hele blaadjie sorgvuldig voordat u begin om PIXICAM 20 te neem
- Hou hierdie blaadjie. U mag nodig kry om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegsuster of ander gesondheidsorgverskaffer.
- PIXICAM 20 is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag hulle skaad, selfs al is hulle simptome dieselfde as u simptome.

Wat is in hierdie blaadjie?

1. Wat PIXICAM 20 is en waarvoor dit gebruik word
2. Wat u nodig het om te weet voordat u PIXICAM 20 neem
3. Hoe om PIXICAM 20 te neem
4. Moontlike newe-effekte
5. Hoe om PIXICAM 20 te berg
6. Inhoud van die pakkie en ander inligting

1. Wat PIXICAM 20 is en waarvoor dit gebruik word
Elke oplosbare tablet bevat piroksikaam 20 mg.
PIXICAM 20 is een van 'n groep medisyne wat nie-steroïdale anti-inflammatoriese (NSAIMs) genoem word.
PIXICAM 20 word gebruik om simptome te verlig wat deur osteoartritis (artrose, degeneratiewe gewrigsiekte), rumatoïede artritis en ankiloserende spondilitis (rumatiek van die werwelkolom) veroorsaak word. Dit sluit swelling, styfheid en gewrigspyn in. Hierdie medisyne genees nie artritis nie en sal u slegs help solank as wat u voortgaan om dit te drink.

U dokter sal PIXICAM 20 slegs vir u voorskryf indien u onbevredigende verligting van simptome met ander NSAIMs gehad het.

2. Wat u nodig het om te weet voordat u PIXICAM 20 neem
Moenie PIXICAM 20 neem nie
- Indien u vir piroksikaam, soortgelyke medisyne genaamd oksikaams, of vir enige van die ander bestanddele in PIXICAM 20 hipersensitief (allergies) is. (Sien asseblief **Wat PIXICAM 20 bevat.**)
- Indien u bloedvormingsafwykings het.
- Indien u ooit vantevore allergies vir asetielsalisielsuur of ander nie-steroïdale anti-inflammatoriese middels (NSAIMs), soos diklofenak of ibuprofeen, was. Allergiese reaksies kan fluitende asemhaling (asma-aanvalle), jeukende loopneus, of uitslag of swelling van die vel insluit.
- Indien u tans 'n maag- of ingewandseer, -bloeding, of -perforasie het of vantevore gehad het.
- Indien u tans afwykings van die maag of dermkanaal het wat aan bloedingsneigings gekoppel is, soos ulseratiewe kolitis, Crohn se siekte, gastro-intestinale kankers of divertikulitis (geïnflammeerde of geïnfekteerde sakkies in die dikderm) of indien u dit vantevore gehad het.
- Indien u ander NSAIMs gebruik, soos ibuprofeen, asook COX-2 selektiewe NSAIMs, soos selekoksib, of asetielsalisielsuur (aspirien), 'n substans wat teenwoordig is in baie medisyne wat gebruik word om pyn te verlig of om koors te verlaag.
- Indien u bloedverdunningsmiddels (antistolmiddels), soos warfarien, gebruik om bloedklonte te voorkom.
- Indien u vantevore 'n ernstige allergiese reaksie van enige aard op enige medisyne gehad het, veral velreaksies soos afskilferende/eksfoliatiewe dermatitis (intense rooiverkleuring van die vel met die vel wat in skubbe of lae afdop), Stevens-Johnsonsindroom (simptome is 'n uitslag, blaasvorming of afskilfering van die vel, mond, oë of genitalieë) of toksiese epidermale nekrolise ('n siekte met blaasvorming en afskilfering van die boonste laag van die vel).
- Indien u vantevore 'n velreaksie (ongeag die felheid) op piroksikaam, ander NSAIMs en ander medisyne gehad het.
- Indien u breinbloeding of ander aktiewe bloeding het of oor die algemeen geneig is om bloeding te ontwikkel.
- Indien u matig tot erge hartversaking het.
- Indien u erge lewer- of nierinkorting het.
- Indien u pyn na 'n hartomleidingsoperasie (CABG) het.
- Indien u in die laaste drie maande van swangerskap is.
- Indien u 'n kind of adolessent onder die ouderdom van 15 jaar is (of indien u so 'n kind of adolessent behandel).

Waarskuwings en voorsorgmaatreëls
Tref spesiale sorg met PIXICAM 20/Spesiale sorg moet met PIXICAM 20 getref word
- Indien u hartprobleme of hoë bloeddruk het.
- Indien u aan geringe tot matige lewersiekte ly. U moenie PIXICAM 20 neem indien u erge lewerinkorting het nie (sien **Moenie PIXICAM 20 neem nie**).
- Indien u aan geringe tot matige niersiekte ly. U moenie PIXICAM 20 neem indien u erge nierinkorting het nie (sien Moenie **PIXICAM 20 neem nie**).
- Indien u sekere bloedvormingsafwykings genaam "porfirie" het.
- Indien u onlangs groot chirurgie gehad het.
- Indien u aan allergieë, hooikoors of asma ly.

Dit mag nodig wees dat u vir opvolgondersoeke by u dokter gaan. Hy/sy sal u inlig hoe gereeld u opgevolg moet word terwyl u behandeling met PIXICAM 20 ontvang.

Potensieel lewensdreigende veluitslae (Stevens-Johnsonsindroom, toksiese epidermale nekrolise) is met die gebruik van PIXICAM 20 gemeld. Dit begin gewoonlik as rooi, teikenagtige kolle of ronde vlekke dikwels met sentrale blase op die romp. Bykomende tekens waarop daar gelet moet word, sluit sere in die mond, keel, neus en genitalieë asook konjunktivitis (rooi en geswelde oë) in. Hierdie potensieel lewensdreigende veluitslae word dikwels deur griepagtige simptome vergesel. Die uitslag mag tot wydverspreide blaasvorming en afskilfering van die vel vorder.
Die grootste risiko vir die verskyning van ernstige velreaksies is binne die eerste weke van behandeling. Indien u Stevens-Johnsonsindroom of toksiese epidermale nekrolise met die gebruik van PIXICAM 20 ontwikkel het, moet u dit nooit weer gebruik nie (sien **Moenie PIXICAM 20 neem nie**).
Ander voorbeelde van ernstige, en soms lewensdreigende, veluitslae sluit afskilferende/eksfoliatiewe dermatitis (uiterste afdopping van die boonste lae van die vel) en gefikseerde middeluitslag (waar die uitslag herverskyn met herblootstelling aan dieselfde medisyne) in. Indien u 'n uitslag of hierdie velsimptome ontwikkel, raadpleeg 'n dokter onmiddellik en lig hom/haar in dat u hierdie medisyne neem.

Medisyne soos PIXICAM 20 mag met 'n klein verhoogde risiko vir 'n hartaanval (miokardiale infarksie) of beroerte geassosieer wees. Enige risiko is meer waarskynlik met hoë dosisse en verlengde behandeling. Moenie die aanbevole dosis of duur van behandeling oorskry nie. Indien u hierdie siektetoestande het of vermoed dat u 'n risiko daarvoor het (u het byvoorbeeld hoë bloeddruk, diabetes of hoë cholesterol of u rook), of as u hartprobleme het of vantevore 'n beroerte gehad het, moet u u behandeling met u dokter of apteker bespreek.

U moet onmiddellik ophou om PIXICAM 20 te neem en u dokter inlig indien u enige allergiese reaksie, soos 'n veluitslag, swelling van die gesig, fluitende asemhaling of moeisame asemhaling, kry.

Wees versigtig met PIXICAM 20 want dit kan, soos alle NSAIMs, ernstige reaksies in die maag en ingewande, soos pyn, bloeding, ulserasie en perforasie, tot gevolg hê.
U moet dadelik ophou om PIXICAM 20 te neem en u dokter inlig indien u maagpyn het of enige teken van bloeding in die maag of ingewande toon, soos die passering van swart of bloedbevlekte stoelgange of as u bloed braak.

U dokter mag PIXICAM 20 saam met ander medisyne (soos misoprostol of protonpompinhibeerders) voorskryf om u maag en ingewande teen newe-effekte te beskerm, veral indien u ouer as 70 jaar is, of indien u ander medisyne gebruik soos kortikosteroïede (medisyne wat gegee word om 'n verskeidenheid van toestande soos allergieë en hormoonwanbalanse te behandel), sekere medisyne vir depressie genaamd selektiewe serotonienheropname-inhibeerders (SSRIs), of asetielsalisielsuur om hartaanvalle en beroerte te help voorkom.

Met die langtermyn gebruik van pynstillers mag hoofpyne voorkom wat nie met hoër dosisse van die pynstillers behandel kan word nie. Vra u dokter vir advies indien u aan hoofpyn ly ten spyte daarvan dat u medisyne gebruik om pyn te behandel.

Die gebruiklike inname van analgetika, veral kombinasies van verskillende pynstillende middels, mag permanente nierskade met die risiko vir nierversaking (analgetiese nefropatie) veroorsaak.

Indien u enige visuele klagtes gedurende behandeling met PIXICAM 20 ontwikkel, moet u vir 'n oogondersoek gaan.

Indien u PIXICAM 20 gebruik en beplan om swanger te raak, veral as u daarmee sukkel of indien u vir infertiliteit ondersoek word, bespreek die moontlike staking van behandeling met PIXICAM 20 met u dokter (**sien ook Swangerskap, borsvoeding en fertiliteit**).

Bejaardes (bo 70-jarige ouderdom)
Ouer persone het 'n verhoogde risiko vir die newe-effekte van NSAIMs, veral bloeding in die maag of ingewande en perforasie.
Indien u ouer as 70 jaar is, mag u dokter dit nodig ag om die duur van u behandeling tot 'n minimum te beperk en om u meer gereeld te evalueer solank as wat u PIXICAM 20 gebruik. U dokter mag PIXICAM 20 saam met ander medisyne voorskryf om u maag en dermkanaal teen moontlike newe-effekte te beskerm (sien hierbo).

U moenie hierdie medisyne drink indien u ouer as 80 jaar is nie.

Kinders en adolessente
Moenie PIXICAM 20 gebruik indien u jonger as 15 jaar van ouderdom is nie.

Ander medisyne en PIXICAM 20
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele geneesmiddels in.)
Die volgende medisyne moenie saam met PIXICAM 20 geneem word nie:
- Asetielsalisielsuur (aspirien) of ander nie-steroïdale anti-inflammatoriese geneesmiddels vir pynverligting
- Bloedverdunners (antistolmiddels), soos warfarien, om bloedklonte te voorkom.

Indien u enige van die volgende medisyne neem, moet u u dokter daarvan inlig voordat u begin om PIXICAM 20 te gebruik:
- Kortikosteroïede, medisyne wat gegee word om 'n verskeidenheid van toestande, soos allergieë, inflammasie en hormoonwanbalanse, te behandel
- Antiplaatjiemedikasie soos lae dosis asetielsalisielsuur (aspirien) om bloedstolling en hartaanvalle of beroerte te help voorkom
- Sekere medisyne, bekend as kardiale glikosiede, soos digoksien, wat gebruik word om harttoestande te behandel
- Sekere medisyne vir depressie, soos litium of selektiewe serotonienheropname-inhibeerders (SSRIs) (sien **Waarskuwings en voorsorgmaatreëls**)
- Medisyne om hoë bloeddruk te behandel
- Metotreksaat, wat gegee kan word om verskeie toestande, soos kanker, psoriase en rumatoïede artritis, te behandel: die kombinasie moet vermy word
- Siklosporien, wat vir die voorkoming van orgaanverwerping na oorplanting gebruik word, maar ook vir die behandeling van rumatiek
- Takrolimus vir die voorkoming van orgaanverwerping na oorplanting
- Diuretika ("waterpille") soos hidrochloortiasied om hoë bloeddruk of nierprobleme te behandel
- Kaliumbesparende medisyne, soos sekere diuretika
- Probenesied, 'n geneesmiddel vir jig
- Simetidien, 'n medisyne om maagsuur te verminder
- Fenitoïen, 'n medisyne vir epilepsie
- Cholestiramien, 'n medisyne om cholesterolvlakke te verlaag
- Mondelingse antidiabetiese middels, soos glimepiried of glipisied, medisyne om verhoogde bloedsuikervlakke te beheer: u moet u bloedsuikervlakke meer gereeld monitor
- Kinoloonantibiotika, soos siprofloksasien, moksifloksasien of levofloksasien, vir die behandeling van bakteriële infeksies
- Mifepristoon vir die beëindiging van swangerskap.

PIXICAM 20 saam met voedsel en drinkgoed en alkohol
Terwyl PIXICAM 20 gebruik word, moet die inname van alkohol vermy word, aangesien dit moontlike newe-effekte mag vererger, veral dié wat die spysverteringskanaal en die sentrale senuweesisteem raak.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of borsvoed, dink dat u swanger mag wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik.

Moenie PIXICAM 20 tydens die laaste drie maande van swangerskap gebruik nie, want dit kan u baba benadeel.
Veiligheid gedurende swangerskap en borsvoeding is nog nie vasgestel nie.
Die aktiewe bestanddeel piroksikaam word in klein hoeveelhede in borsmelk uitgeskei. Die gebruik van PIXICAM 20 word nie tydens borsvoeding aanbeveel nie.
NSAIMs, soos PIXICAM 20, mag met die vrystelling van eiers vanaf die eierstokke inmeng (sien **Waarskuwings en voorsorgmaatreëls**).

Bestuur en die gebruik van masjiene
PIXICAM 20 kan sommige mense duiselig, lomerig of moeg maak of probleme met hulle visie veroorsaak. Indien u geaffekteer is, moenie bestuur of masjiene gebruik nie.

PIXICAM 20 bevat suiker (laktosemonohidraat)
PIXICAM 20 bevat 'n bestanddeel genaamd laktose (melksuiker). Indien u laktose-onverdraagsaam is, galaktose-onverdraagsaam is of glukose-galaktose-wanabsorpsie het, lig u dokter daaroor in voordat u PIXICAM 20 gebruik.

3. Hoe om PIXICAM 20 te neem
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Gebruik PIXICAM 20 altyd presies soos wat u dokter u opdrag gegee het. Raadpleeg u dokter of apteker indien u onseker is.

U dokter sal u gereeld monitor om seker te maak dat u die optimale dosis PIXICAM 20 gebruik. U dokter sal u behandeling aanpas tot by die laagste dosis wat u simptome die beste beheer om so moontlike newe-effekte tot 'n minimum te beperk. U moet onder geen omstandighede u dosis verander sonder om dit eers met u dokter te bespreek nie.

Die tablette mag heel met genoegsame water gesluk word of mag in 'n klein hoeveelheid water in 'n glas opgelos word waarna die oplossing dan gesluk word.

Volwassenes
Die gewone daaglike dosis PIXICAM 20 is 20 milligram geneem as 'n enkele daaglikse dosis. Die maksimum daaglikse dosis is 40 mg (in 'n enkele of verdeelde dosisse) vir die korttermyn behandeling van akute spier- of beentoestande of akute jig.

Bejaardes
Indien u ouer as 70 jaar is, mag u dokter 'n laer daaglikse dosis voorskryf en die duur van behandeling verkort.
U dokter sal u inlig hoe lank behandeling met PIXICAM 20 sal duur. Indien u die indruk het dat die effek van PIXICAM 20 te sterk of te swak is, lig asseblief u dokter of apteker in.

Indien u meer PIXICAM 20 geneem het as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Simptome van oordosering mag hoofpyn, duiseligheid, lomerigheid, maagpyn, naarheid, braking en hiperventilasie insluit.

Indien u vergeet om PIXICAM 20 te neem
Indien u vergeet om 'n dosis te neem, neem dit so gou as wat u dit onthou, tensy dit tyd vir u volgende dosis is. Moenie 'n dubbele dosis neem om vir 'n vergete dosis te vergoed nie.
Indien u enige verdere vrae oor die gebruik van hierdie medisyne het, vra u dokter of apteker.

4. Moontlike newe-effekte
PIXICAM 20 kan newe-effekte hê.
Nie alle newe-effekte wat vir PIXICAM 20 gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of indien u enige ongunstige effekte ervaar terwyl u hierdie medisyne neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Lig u dokter onmiddellik in en hou op om PIXICAM 20 te gebruik indien u enige van die volgende simptome ervaar nadat u hierdie medisyne geneem het:
- Enige teken van bloeding in die maag of ingewande, soos die passerig van swart (teeragtige) of bloedbevlekte stoelgange of die braking van bloed
- Skielike fluitende asemhaling, moeisame asemhaling, koors, swelling van die ooglede, gesig of lippe, uitslag of jeuk (veral as dit die hele liggaam affekteer)
- Potensieel lewensdreigende veluitslae insluitende vel wat afdop, veral rondom die mond, neus, oë en genitalieë (Stevens-Johnsonsindroom) of uitgebreide afdopping van die vel (toksiese epidermale nekrolise) (sien **Waarskuwings en voorsorgmaatreëls**)
- Geelverkleuring van die vel en die wit van die oë (geelsug) wat 'n teken van lewerontsteking of ander lewerprobleme mag wees.

Ander newe-effekte wat tydens die gebruik van hierdie medisyne ervaar mag word, is:
Newe-effekte wat dikwels voorkom:
- Verlaging in rooibloedselle wat die vel bleek mag maak en swakheid of kortasemheid mag veroorsaak
- Hoë vlakke van 'n spesifieke tipe witbloedsel (eosinofilie)
- Veranderinge in witbloedseltellings wat 'n verhoogde risiko vir infeksie tot gevolg mag hê (leukopenie) of trombositopenie (afname in bloedplaatjies) wat die risiko vir bloeding of kneusing mag verhoog
- Eetlusverlies
- Styging in bloedsuikervlakke
- Duiseligheid, hoofpyn, slaperigheid
- 'n Gevoel van duiseligheid of draaiing
- Gesuis in die ore (tinnitus)
- Maagpyn/ongemak, hardlywigheid
- Diarree (loopmaag), winderigheid, siek voel (naarheid), braking, slegte spysvertering
- Jeuk, veluitslag
- Swelling van die enkels, voete of vingers (edeem)
- Styging in lewerensieme
- Abnormale nierfunksietoetsuitslae
- Gewigstoename.

Newe-effekte wat minder dikwels voorkom:
- Verlaagde/lae bloedsuikervlakke wat flouheid, honger, sweet of bewerigheid mag veroorsaak
- Dowwe visie
- Bewus wees van u hartklop
- Seer mond en/of lippe.

Nie bekend nie – frekwensie kan nie uit die beskikbare data geskat word nie
- Abnormaliteite in die bloed soos erge verlagings in bloedselle wat swakheid of kneusing mag veroorsaak of infeksies meer waarskynlik mag maak (aplastiese anemie)
- Vogterughouding
- Depressie, abnormale drome, hallusinasies, moeite om te slaap, verstandelike verwarring, gemoedsveranderinge, senuweeagtigheid
- Tinteling of gevoelloosheid (parestesie)
- Oogirritasie of geswelde oë
- Swarigheid om te hoor
- Hartversaking met tekens soos kortasemheid, moeisame asemhaling wanneer plat gelê word, swelling van die voete of bene
- Inflammasie van die bloedvate
- Hoë bloeddruk
- Vorming van bloedklonte in bloedvate; hartaanval (miokardiale infarksie) of beroerte
- Moeisame asemhaling of fluitende asemhaling
- Neusbloeding
- Inflammasie van die maagbelyning (gastritis)
- Inflammasie van die pankreas (wat tot erge pyn in die bobuik of rug mag lei)
- Gastro-intestinale ulkusse en/of perforasie
- Vergergering van kolitis en Crohn se siekte
- Sere in die mond
- Inflammasie van die lewer (fatale hepatitis)
- Haarverlies
- Allergiese reaksie wat pers kolle op die vel, gewrigspyn, buikpyn en nierdisfunksie behels (Henoch-Schoenlein purpura)
- Loslating of skeuring van vingernaels
- Verhoogde sensitiwiteit van die vel vir sonlig
- Niersiekte, nierinflammasie, nierversaking
- Verlaagde fertiliteit in vrouens
- Algemeen ongesteld voel.

Indien u enige newe-effekte opmerk wat nie in hierdie blaadjie genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte kry, gesels met u dokter, apteker of verpleegsuster. U kan newe-effekte ook aan die SARGP via die "**6.04 Adverse Drug Reaction Reporting Form**" rapporteer; dit kan aanlyn onder die SARGP se publikasies by https://www.sahpra.org.za/Publications/Index/8 gevind word.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van PIXICAM 20 te voorsien.

5. Hoe om PIXICAM 20 te berg
- Bewaar alle medisyne buite die bereik van kinders.
- Berg teen of benede 25 °C. Beskerm teen lig.
- Moenie die tablette na die vervaldatum wat op die houer, stulpstrook of etiket gedruk is, gebruik nie.
- Besorg alle ongebruikte medisyne aan u apteker terug.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Wat PIXICAM 20 bevat
Die aktiewe bestanddeel is piroksikaam.
Die ander bestanddele is kolloïdale anhidriese silika, krospovidoon, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose en natriumdodesielsulfaat.

Hoe PIXICAM 20 lyk en inhoud van die pakkie
PIXICAM 20 is 'n uniforme, wit tot ligte geel, ronde, bikonvekse 9 mm x 4 mm tablet met 'n breeklyn.
PIXICAM 20 is beskikbaar in wit, HDPE-sekuriteitshouers of polipropileenfoelie-stulpstroke in pakkies van 30 en 100 oplosbare tablette.

Houer van die Sertifikaat van Registrasie
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