Patient Information Leaflet

SCHEDULING STATUS:

S3

COLCIBRA 100 mg, hard capsules

COLCIBRA 200 mg, hard capsules

Celecoxib

Contains sugar (lactose monohydrate

Read all of this leaflet carefully before you start taking COLCIBRA

- 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.
- **COLCIBRA** 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 **COLCIBRA** is and what it is used for.

2. What you need to know before you take **COLCIBRA**.

3. How to take **COLCIBRA**.

4. Possible side effects.

5. How to store **COLCIBRA**.

6. Contents of the pack and other information.

1. What COLCIBRA is and what it is used for.

COLCIBRA belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), and specifically a sub-group known as cyclooxygenase-2 (COX-2) inhibitors.
Your body makes substances called prostaglandins. Some prostaglandins may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. **COLCIBRA** acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

COLCIBRA is used in adults for the relief of signs and symptoms of the following conditions: rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis (progressive stiffening of the spine).

COLCIBRA is also used in the treatment of pain following an operation, including dental surgery, musculoskeletal pain, and primary dysmenorrhoea (painful menstrual periods).

2. What you need to know before you take COLCIBRA

Do not take COLCIBRA:

- if you are hypersensitive (allergic) to celecoxib or any of the ingredients of **COLCIBRA** (see section 6 “What this product contains”);
- if you have had an allergic reaction to a group of medicines called “sulfonamides” (medicines that prevent the growth of bacteria);
- if you have severe liver disease.
- if you have severe kidney disease.
- if you have had allergic reactions such as asthma, nose polyps, severe nasal congestion, or an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing from aspirin or other NSAIDs (anti-inflammatory and pain-relieving medicines, such as diclofenac, ibuprofen);
- established ischaemic heart disease, or cerebrovascular disease, e.g. you have

been diagnosed with a heart attack, stroke, or blockages of blood vessels to the heart or brain;

- if you are about to have coronary artery bypass graft surgery;
- if you currently have an ulcer in your stomach or intestines, or if you are bleeding in your stomach or intestines (you may notice that you have black sticky stools or bloody diarrhoea);
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease;
- if you are pregnant or it is possible that you could become pregnant;
- if you are breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking **COLCIBRA.**

Take special care with **COLCIBRA:**

- if you smoke, have diabetes, high blood pressure or high blood cholesterol;
- if you have had a serious allergic reaction or a serious skin reaction to any medicines;
- if you have previously had an ulcer or bleeding in your stomach or intestines. (Do not take **COLCIBRA** if you currently have an ulcer or bleeding in your stomach or intestine);
- if you are taking corticosteroid medicines (for example prednisone);
- if you are taking aspirin (even at low dose for heart protective purposes);
- if you use medicines to reduce blood clotting (e.g. warfarin/warfarin like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban).
- if you are taking **COLCIBRA** at the same time as other non-aspirin NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided;
- if you have fluid retention (such as swollen ankles and feet);
- if you have heart failure or other heart problems;

- if you have high blood pressure;
- if your liver or kidneys are not working well, as your doctor may want to keep a regular check on you;
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (medicines used to get rid of excess fluid in the body);
- if you feel ill due to an infection, or think you have an infection, as **COLCIBRA** may mask a fever or other signs of infection and inflammation

If you are above 65 years of age your doctor will want to monitor you regularly.

The consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems.

COLCIBRA may lead to an increase in blood pressure. Your doctor may want to monitor your blood pressure on a regular basis.

Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome or requiring liver transplant), have been reported with celecoxib. Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.

Other medicines and COLCIBRA:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Before you take **COLCIBRA**, make sure your doctor knows if you are taking the following medicines:

- Warfarin (used to prevent blood from clotting)
- ACE inhibitors, angiotensin II receptor antagonists, beta blockers (used for high blood pressure and heart failure)

- Diuretics (used to treat fluid retention)
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants).
- Aspirin (used for pain and fever). **COLCIBRA** can be taken with low dose aspirin (75 mg or less daily). Ask your doctor for advice before taking both medicines together **COLCIBRA** has no antiplatelet effect and is therefore not a substitute for aspirin for prevention of thrombosis
- Neuroleptics (used to treat some mental disorders)
- Medicines for anxiety (diazepam) or to treat depression (citalopram, imipramine)
- Medicines to treat an irregular heartbeat (amiodarone, quinidine)
- Dextromethorphan (used to treat coughs)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Lithium (used to treat some types of depression)
- Oral contraceptives
- Glibenclamide, tolbutamide (medicines used in the management of type 2 diabetes)
- Phenytoin, a medicine used in epilepsy (seizure disorder)
- Fluconazole (used to treat fungal infection)
- Rifampicin (used to treat bacterial infections)
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression)
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)
- Ketoconazole (an antifungal medicine)
- Antacids (used for heartburn).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **COLCIBRA**.

Pregnancy

COLCIBRA must not be used by women who are pregnant or can become pregnant (i.e. women of child bearing potential who are not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with **COLCIBRA**, you should discontinue the treatment and contact your doctor for alternative treatment.

Breast-feeding

COLCIBRA must not be used during breastfeeding.

Fertility

NSAIDs, including **COLCIBRA**, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machinery:

You should be aware of how you react to **COLCIBRA** before you drive or operate machinery. If you feel dizzy or drowsy after taking **COLCIBRA**, do not drive or operate machinery until these effects wear off.

COLCIBRA contains lactose

COLCIBRA contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **COLCIBRA**.

3. How to take COLCIBRA:

Do not share medicines prescribed for you with any other person.

Always take **COLCIBRA** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you think or feel that the effect of **COLCIBRA** is too strong or too weak, talk to your doctor or pharmacist.

Use the lowest effective dose for the shortest possible time.

Your doctor will tell you what dose to take.

The recommended dose for osteoarthritis is 200 mg taken as a single dose, or as two divided doses.

The recommended dose for rheumatoid arthritis is 100 mg or 200 mg twice daily.

The recommended dose for pain following dental surgery is 100 mg or 200 mg twice daily.

The recommended dose for pain following an operation is 200 mg once daily.

The recommended dose for musculoskeletal pain is 200 mg twice daily.

The recommended dose for primary dysmenorrhoea is 400 mg initially, followed by an additional 200 mg on the first day if needed. On subsequent days, the recommended dose is 200 mg twice daily.

The recommended dose for ankylosing spondylitis is 200 mg daily, taken as a single dose or as 100 mg twice daily.

If you have liver problems, or if you weigh less than 50 kg, your doctor will recommend the lowest recommended dose.

Children:

No information is available on the use of **COLCIBRA** in children and it is therefore not recommended for use in children.

Method of administration:

COLCIBRA is for oral use. Swallow the capsules whole with a glass of water at any time of the day, with or without food. However, try to take each dose of **COLCIBRA** at the same time each day. Do not chew or crush the granules.

Contact your doctor within two weeks of starting treatment if you do not experience any benefit.

If you take more COLCIBRA than you should:

You should not take more capsules than your doctor tells you to.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take COLCIBRA:

If you forget to take a capsule, take it as soon as you remember.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking COLCIBRA

Suddenly stopping your treatment with **COLCIBRA** may lead to your symptoms getting worse. Do not stop taking **COLCIBRA** unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

COLCIBRA can have side effects.

Not all side effects reported for **COLCIBRA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **COLCIBRA**, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking COLCIBRA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- a serious skin reaction with rash, blistering or peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to **COLCIBRA**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- weakness or clumsiness of a hand, arm or leg, difficulties with speech and swallowing, vision problems and headache. These may be signs of a stroke or bleeding in the brain, which may be fatal.
- shortness of breath or difficulty breathing, sudden chest pain,
- cramping or tingling sensation up the left arm (heart attack)
- problems breathing, shortness of breath, chest pain. You may have a blood clot in the lung (pulmonary embolism) and will need urgent medical attention
- throbbing or cramping pain in a leg, swelling in a leg, warm skin around painful area (deep vein thrombosis)
- severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood
- liver failure (symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow)
- bladder or kidney infections. Some signs may be fever, chills, blood in the urine or frequent urination

- acute renal failure/nephrotic syndrome (decreased urine output, swelling of legs, fatigue, foamy urine, loss of appetite)
- painful blisters, sensitive to touch (shingles)
- red, swollen, painful skin with fever (a bacterial skin infection, known as erysipelas)
- ache or burning pain in your abdomen (Helicobacter infection).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- infections of the airways such as sinusitis (swelling and redness of the nasal sinuses) or bronchitis (inflammation of the mucous membranes of the airways)
- worsening of existing allergies
- weight gain
- trouble sleeping
- dizziness, abnormal muscle tension
- headache
- high blood pressure, worsening of existing high blood pressure. You may not know that you have high blood pressure unless you have your blood pressure tested.
- runny nose, sore throat, shortness of breath.
- nausea (feeling sick), vomiting (being sick)
- indigestion, windiness, pain on stomach
- problem swallowing
- sore teeth
- skin rash, itching skin.
- accidental injury.

- flu-like illness
- keeping fluid back in the body tissues, with swollen ankles, legs and/or hands.

Less frequent side effects

- inflammation or infection of the inner ear (dizziness or feeling that everything is spinning around you)
- infection of the gums
- blood disorders, such as anaemia (too few red blood cells or their haemoglobin content is too low), leukopenia (a lowered white blood cell count) or thrombocytopenia (deficiency of platelets in the blood)*

*You will only know that you have these disorders if your doctor orders blood tests. See your doctor if you are pale and tired, get more infections than usual or have problems to stop bleeding, or if you have unexpected bruising

- increased sodium in blood, increased potassium in blood (determined by blood tests)
- feeling tired, confused
- feeling anxious or depressed
- seeing or hearing things that do not exist (hallucinations)
- blurred vision, eye inflammation and bloodshot eyes, vitreous floaters (seeing spots or strings that move when you move your eyes), bleeding in an eye, painful eyes
- ringing in the ears, above normal hearing sense, voice disorder
- irregular heart rhythm, increased heart rate
- flushing inflammation of a blood vessel (you may feel unwell with fever, sweats and tiredness)
- tightness in the chest with coughing and wheezing (bronchospasm)
- shortness of breath, cough, fatigue (inflammation of the lung tissues - pneumonitis)
- abdominal pain, cramping, bloating, constipation
- mouth ulcers, numbness, burning sensation in the mouth (stomatitis)

- hair loss
- muscle spasms (leg cramps), muscle pain
- lower limb fracture
- kidney function disorders (shown by laboratory tests)
- frequent urination during the night (nocturia)
- menstrual disorders
- swollen face
- chest pain.

Frequency unknown

- sleepiness
- abnormal skin sensations (tingling or tickling or itching or burning)
- problems with coordination and speech (ataxia)
- no sense of smell or taste, or taste affected
- worsening of existing epilepsy (seizure disorder)
- female fertility decreased
- vaginal bleeding
- tender breasts.

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 By reporting side effects, you can help provide more information on the safety of **COLCIBRA.**

5. How to store COLCIBRA

Store all medicine out of reach of children.

Store at or below 25 °C.

Do not use this medicine after the expiry date stated on the carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COLCIBRA contains

The active substance is celecoxib.

1 Capsule contains 100 mg or 200 mg celecoxib.

The other ingredients are:

Lactose monohydrate

Povidine

Colloidal Anhydrous Silica

Sodium Lauryl Sulphate

Crosscarmellose Sodium

Magnesium Stearate

Purified Water.

What COLCIBRA looks like and contents of the pack

COLCIBRA 100:

Opaque, white to off white hard gelatin capsules imprinted with 'CC' on cap and '100' on body of capsules shell with black ink, containing white to off white granular powder and/or compacted mass.

COLCIBRA 200:

Opaque, white to off white hard gelatin capsules imprinted with 'CC' on cap and '200' on body of capsules shell with black ink, containing white to off white granular powder and/or compacted mass.

COLCIBRA Capsules are packed in Aclar/PVC/Alu blister packs. Blisters containing 30 and 60 capsules are packed in a carton along with a package leaflet.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stomill, Ext 1

Roodepoort, 1724

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COLCIBRA Pasiëntinligtingsbrosjure

SKEDULERINGSSTATUS:

S3

COLCIBRA 100 mg (Kapsules)

COLCIBRA 200 mg (Kapsules)

Selekoksib

Bevat suiker (laktose monohidraat)

Lees die hele brosjure aandagtig deur voordat u COLCIBRA begin gebruik

- Hou hierdie pamflet. Miskien moet u dit weer lees.
- Vra u dokter of apteker as u nog vrae het.
- **COLCIBRA** is persoonlik aan u voorgeskryf en u moet u medisyne nie met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat is **COLCIBRA** en waarvoor word dit gebruik.
2. Wat u moet weet voordat u **COLCIBRA** neem.
3. Hoe om **COLCIBRA** in te neem.
4. Moontlike newe -effekte.
5. Hoe om **COLCIBRA** te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat COLCIBRA is en waarvoor dit gebruik word.

COLCIBRA behoort tot 'n groep medisyne genaamd nie-steroïdale anti-inflammatoriese middels (NSAIM's), en spesifiek 'n subgroep bekend as siklooksigenase-2 (COX-2) remmers. Jou liggaam maak stowwe wat prostaglandiene genoem word. Sommige prostaglandiene kan pyn

en ontsteking veroorsaak. n toestande soos rumatoïede artritis en osteoartritis maak u liggaam meer hiervan. **COLCIBRA** werk deur die produksie van prostaglandiene te verminder, waardeur die pyn en ontsteking verminder word.

COLCIBRA word gebruik by volwassenes vir die verligting van tekens en simptome van rumatoïede artritis, osteoartritis en ankiloserende spondilitis (progressiewe verstywing van die ruggraat). COLCIBRA word ook gebruik vir die behandeling van pyn na 'n operasie, insluitend tandheelkundige chirurgie, muskuloskeletale pyn, primêre dismenorree (pynlike menstruasie).

2. Wat u moet weet voordat u COLCIBRA neem.

Moet nie COLCIBRA neem:

- as u hipersensitief (allergies) is vir selekoksib of enige van die bestanddele van COLCIBRA (sien afdeling 6 "Wat bevat hierdie produk");
- as u 'n allergiese reaksie gehad het vir 'n groep medisyne genaamd "sulfoonamiede" (medisyne wat die groei van bakterieë voorkom);
- as u 'n ernstige lewersiekte het.
- as u 'n ernstige niersiekte het.
- as u allergiese reaksies gehad het soos asma, poliepe in die neus, erge neusverstopping of 'n jeukende veluitslag, swelling van die gesig, lippe, tong of keel, asemhalingsprobleme of asemhaling vir aspirien of ander NSAIMs (anti-inflammatoriese en pynverligtende medisyne), soos diklofenak, ibuprofen);
- gevestigde isgemiese hartsiektes, of serebrovaskulêre siektes, bv. as u gediagnoseer is met 'n hartaanval, beroerte of blokkasies van bloedvate na die hart of brein;
- as u op die punt staan om 'n chirurgie vir die omleiding van kransslagare te ondergaan;

- as u tans 'n ulkus in u maag of ingewande het, of as u bloeding in u maag of ingewande het (u kan sien dat daar 'n swart, taai stoelgang of bloedige diarree is);
- as u 'n inflammatoriese siekte van die ingewande het, soos ulseratiewe kolitis of Crohn se siekte;
- as u swanger is of moontlik swanger kan raak;
- as u borsvoed.

Waarskuwings en voorsorgmaatreëls

Praat met jou dokter of apteker voordat jy COLCIBRA neem

Wees veral versigtig met COLCIBRA:

- as u rook, diabetes, hoë bloeddruk of hoë cholesterol in die bloed het;
- as u 'n ernstige allergiese reaksie of 'n ernstige velreaksie op enige medisyne gehad het;
- as u voorheen 'n ulkus of bloeding in u maag of ingewande gehad het. (Moenie **COLCIBRA** neem as u tans 'n ulkus of bloeding in u maag of ingewande het nie);
- as u kortikosteroïed medisyne gebruik (byvoorbeeld prednisoon);
- as u aspirien neem (selfs teen 'n lae dosis vir hartbeskermingsdoeleindes);
- as u medisyne gebruik om bloedstolling te verminder (bv. warfarien/warfarien soos antistolmiddels of nuwe orale antistollingsmedisyne, bv. Apixaban).
- as u **COLCIBRA** gelyktydig gebruik met ander nie-aspirien NSAIM's, soos ibuprofen of diklofenak. Die gesamentlike gebruik van hierdie medisyne moet vermy word;
- as u vloeistofretensie het (soos geswelde enkels en voete);
- as u hartversaking of ander hartprobleme het;
- as u hoë bloeddruk het;
- as u lewer of niere nie goed werk nie, aangesien u dokter u gereeld wil kontroleer;

- as u gedehidreerd is, byvoorbeeld weens siekte, diarree of die gebruik van diuretika (medisyne wat gebruik word om oortollige vloeistof in die liggaam te verwyder);
- as u siek voel as gevolg van 'n infeksie, of as u dink dat u 'n infeksie het, aangesien **COLCIBRA** koors of ander tekens van infeksie en ontsteking kan verdoesel.

As u ouer as 65 is, sal u dokter u gereeld wil monitor.

Die gebruik van alkohol en NSAIM's kan die risiko van gastro -intestinale probleme verhoog.

COLCIBRA kan lei tot 'n toename in bloeddruk. U dokter sal u bloeddruk gereeld wil monitor.

Sommige gevalle van ernstige lewerreaksies, insluitend ernstige lewerontsteking, lewerskade, lewerversaking (sommige met 'n noodlottige uitkoms of wat leweroorplanting benodig), is aangemeld met selekoksib. Van die gevalle wat tyd tot aanvang gerapporteer het, het die ernstigste lewerreaksies binne een maand na die aanvang van die behandeling plaasgevind.

Ander medisyne en COLCIBRA:

Vertel altyd u gesondheidsorgverskaffer as u ander medisyne gebruik (dit sluit aanvullende of tradisionele medisyne in).

Vertel u dokter as u een van die volgende medisyne gebruik:

- Warfarien (gebruik om te verhoed dat bloed stol)
- ACE -remmers, angiotensien II -reseptorantagoniste, beta -blokkers (gebruik vir hoë bloeddruk en hartversaking)
- Diuretika (gebruik om vloeistofretensie te behandel)
- Siklosporien en takrolimus (gebruik vir immuunstelselonderdrukking, bv. na oorplantings).

- Aspirien (gebruik vir pyn en koors). **COLCIBRA** kan geneem word met 'n lae dosis aspirien (75 mg of minder daagliks). Vra u dokter om advies voordat u albei medisyne saam gebruik.
- Neuroleptika (gebruik vir die behandeling van sommige geestesversteurings)
- Medisyne vir angs (diasepam) of vir die behandeling van depressie (sitalopram, imipramien)
- Medisyne vir die behandeling van 'n onreëlmatige hartklop (amiodaroon, kinidien)
- Dekstrometorfan (gebruik vir die behandeling van hoes)
- Metotreksaat (gebruik vir die behandeling van rumatoïede artritis, psoriase en leukemie)
- Litium (gebruik vir die behandeling van sekere soorte depressie)
- Mondelinge voorbehoedmiddels
- Glibenklamied, tolbutamied (medisyne wat gebruik word vir die behandeling van tipe 2 - diabetes)
- Fenitoïen, 'n medisyne wat gebruik word vir epilepsie (aanvalle)
- Flukonasool (gebruik vir die behandeling van swaminfeksies)
- Rifampisien (gebruik vir die behandeling van bakteriële infeksies)
- Karbamasepien (gebruik vir die behandeling van epilepsie/aanvalle en sommige vorme van pyn of depressie)
- Barbiturate (gebruik vir die behandeling van epilepsie/aanvalle en sommige slaapstoornisse)
- Ketokonasool ('n antifungale middel)
- Teensuurmiddels (gebruik vir sooibrand).

Swangerskap, borsvoeding en vrugbaarheid

As u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg u dokter of apteker voordat u hierdie medisyne neem.

Swangerskap

COLCIBRA mag nie gebruik word deur vroue wat swanger is of swanger kan word nie (dws vroue wat swanger kan word en wat nie voldoende voorbehoeding gebruik nie) tydens voortgesette behandeling.

As u swanger raak tydens die behandeling met **COLCIBRA**, moet u die behandeling staak en u dokter kontak vir alternatiewe behandeling.

Borsvoeding

COLCIBRA moet nie gedurende borsvoeding gebruik word nie.

Vrugbaarheid

NSAIMs, insluitend **COLCIBRA**, kan dit moeiliker maak om swanger te raak. U moet u dokter inlig as u van plan is om swanger te raak of as u probleme ondervind om swanger te raak.

Bestuur en gebruik van masjinerie:

U moet weet hoe u op **COLCIBRA** reageer voordat u bestuur of masjinerie bestuur. As u duiselig of slaperig voel nadat u **COLCIBRA** geneem het, moet u nie bestuur of masjinerie bestuur totdat hierdie effekte verdwyn het nie.

COLCIBRA bevat laktose

COLCIBRA bevat laktose ('n tipe suiker). As u dokter u meegedeel het dat u sommige suikers nie verdra nie, moet u u dokter kontak voordat u **COLCIBRA** neem.

3. Hoe om COLCIBRA te neem

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.

Gebruik **COLCIBRA** altyd presies soos u dokter of apteker u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.

Raadpleeg u dokter of apteker as u dink of voel dat die effek van COLCIBRA te sterk of te swak is. Gebruik die laagste effektiewe dosis vir die kortste moontlike tyd. Jou dokter sal jou vertel watter dosis jy moet neem.

Die aanbevole dosis vir osteoartritis is 200 mg as 'n enkele dosis, of as twee verdeelde dosisse.

Die aanbevole dosis vir rumatoïede artritis is 100 mg of 200 mg twee keer per dag.

Die aanbevole dosis vir pyn na tandheelkundige chirurgie is 100 mg of 200 mg twee keer per dag.

Die aanbevole dosis vir pyn na 'n operasie is 200 mg een keer per dag.

Die aanbevole dosis vir muskuloskeletale pyn is 200 mg twee keer per dag.

Die aanbevole dosis vir primêre dismenorree is aanvanklik 400 mg, gevolg deur 'n ekstra 200 mg op die eerste dag indien nodig. Op die daaropvolgende dae is die aanbevole dosis 200 mg twee keer per dag.

Die aanbevole dosis vir ankiloserende spondilitis is 200 mg daagliks, as 'n enkele dosis of as 100 mg twee keer per dag.

As u lewerprobleme het, of as u minder as 50 kg weeg, sal u dokter die laagste aanbevole dosis aanbeveel.

Kinders:

Daar is geen inligting beskikbaar oor die gebruik van **COLCIBRA** by kinders nie, en dit word dus nie aanbeveel vir gebruik by kinders nie.

Metode van toediening:

COLCIBRA is vir orale gebruik. Sluk die kapsules heel met 'n glas water op enige tyd van die dag, met of sonder kos.

Probeer egter om elke dosis **COLCIBRA** elke dag op dieselfde tyd te neem. Moenie die korrels kou of breek nie.

Kontak u dokter binne twee weke na die aanvang van die behandeling as u geen voordeel daaruit trek nie.

As u meer COLCIBRA neem as wat u moet

U moet nie meer kapsules neem as wat u dokter u voorgeskryf het nie.
Raadpleeg u dokter of apteker in geval van oordosis. As daar nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As u vergeet om COLCIBRA te neem:

As u vergeet om 'n kapsule te neem, neem dit sodra u onthou.
Moenie 'n dubbele dosis neem om die vergete individuele dosisse in te haal nie.

As u ophou om COLCIBRA te neem

As u skielik die behandeling met **COLCIBRA** staak, kan u simptome erger word.
Moenie ophou om **COLCIBRA** te neem nie, tensy u dokter u aangesê het. U dokter kan u vertel om die dosis oor 'n paar dae te verminder voordat u heeltemal stop. Raadpleeg u dokter of apteker as u nog vrae het oor die gebruik van hierdie medisyne.

4. Moontlike newe -effekte

COLCIBRA kan newe -effekte hê. Nie alle newe -effekte wat vir **COLCIBRA** aangemeld is, is in hierdie pamflet ingesluit nie. Raadpleeg u gesondheidswerker vir advies as u algemene gesondheid versleg of as u nadelige gevolge ondervind tydens die gebruik van **COLCIBRA.**

As een van die volgende gebeur, moet u ophou om COLCIBRA te neem en dit onmiddellik aan u dokter te vertel of na die ongevalle-afdeling in u naaste hospitaal te gaan:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.
- 'n ernstige velreaksie met uitslag, blase of afskilfering van die vel.

Dit is alles baie ernstige newe -effekte. As u dit ondervind het, het u moontlik 'n ernstige reaksie op **COLCIBRA** gehad. U benodig moontlik dringend mediese aandag of hospitalisasie.

Lig u dokter onmiddellik in of gaan na die ongevalle -afdeling in u naaste hospitaal as u een van die volgende opmerk:

- swakheid of lompheid van 'n hand, arm of been, probleme met spraak en sluk, visieprobleme en hoofpyn. Dit kan tekens wees van 'n beroerte of bloeding in die brein, wat dodelik kan wees.
- kortasem of asemhalingsprobleme, skielike pyn op die bors,
- krampe of tinteling-sensasie in die linkerarm (hartaanval)
- asemhalingsprobleme, kortasem, pyn op die bors. U het moontlik 'n bloedklont in die long (longembolie) en benodig dringend mediese hulp
- kloppende of krampagtige pyn in 'n been, swelling in 'n been, warm vel rondom pynlike gebied (diep veneuse trombose)
- erge maagpyn of enige teken van bloeding in die maag of ingewande, soos swart of bloedbesmette stoelgang, of bloed braking
- lewerversaking (simptome kan naarheid, diarree, geelsug (u vel of die wit van u oë lyk geel), insluit)
- blaas- of nierinfeksies. Sommige tekens kan koors, kouekoors, bloed in die urine of gereelde urinering wees

- akute nierversaking/nefrotiese sindroom (verminderde urienuitset, swelling van die bene, moegheid, skuimagtige urien, verlies aan eetlus)
- pynlike blase, sensitief vir aanraking (gordelroos)
- rooi, geswelde, pynlike vel met koors ('n bakteriese velinfeksie, bekend as erisipelas)
- pyn of brandende pyn in u buik (Helicobacter -infeksie).

Dit is alles ernstige newe -effekte. U mag dringende mediese aandag benodig.

Vertel u dokter as u een van die volgende opmerk:

Gereelde newe -effekte:

- infeksies van die lugweë soos sinusitis (swelling en rooiheid van die nasale sinusse) of brongitis (ontsteking van die slymvliese van die lugweë)
- Verergering van bestaande allergieë
- gewigstoename
- sukkel om te slaap
- duiseligheid, abnormale spierspanning
- hoofpyn
- hoë bloeddruk, verergering van bestaande hoë bloeddruk. U weet miskien nie dat u hoë bloeddruk het nie, tensy u u bloeddruk laat toets.
- loopneus, seer keel, kortasem.
- naarheid (siek gevoel), braking
- slegte spysvertering, winderigheid, maagpyn
- probleem met sluk
- seer tande
- veluitslag, vel jeuk.
- toevallige besering.
- griepagtige siekte
- hou vloeistof terug in die liggaamsweefsel, met geswelde enkels, bene en/of hande.

Minder gereelde newe -effekte

- ontsteking of infeksie van die binneoor (duiseligheid of gevoel dat alles om jou draai)
- infeksie van die tandvleis
- bloedafwykings, soos bloedarmoede (te min rooibloedselle of hul hemoglobieninhoud is te laag), leukopenie ('n verlaagde aantal witbloedselle) of trombositopenie (tekort aan bloedplaatjies)*

*U sal slegs weet dat u hierdie siektes het as u dokter bloedtoetse aanbeveel. Raadpleeg u dokter as u bleek en moeg is, meer infeksies kry as gewoonlik of probleme ondervind om bloeding te stop, of as u onverwagte kneusplekke het.

- verhoogde natrium in bloed, verhoogde kalium in bloed (bepaal deur bloedtoetse)
- moegheid, verward
- angstig of depressief voel
- dinge sien of hoor wat nie bestaan nie (hallusinasies)
- versteurde visie, oogontsteking en bloedbelope oë, glasagtige drywers (sien kolle of snare wat beweeg as jy jou oë beweeg), bloeding in 'n oog, pynlike oë
- fluitgeluid in die ore, bo normale gehoorsin, stemversteuring
- onreëlmatige hartritme, verhoogde hartklop
- ontsteking van 'n bloedvat (u kan sleg voel met koors, sweet en moegheid)
- benoudheid in die bors met hoes en asemhaling (brongospasme)
- kortasem, hoes, moegheid (ontsteking van die longweefsel - pneumonitis)
- buikpyn, krampe, opgeblasenheid, hardlywigheid
- mondsere, gevoelloosheid, brandgevoel in die mond (stomatitis)
- haarverlies
- spierspasmas (beenkrampe), spierpyn
- fraktuur van die onderste ledemate
- nierfunksie afwykings (getoon deur laboratoriumtoetse)

- gereelde urinering gedurende die nag (nocturia)
- menstruele afwykings
- geswelde gesig
- borspyn.

Frekwensie onbekend

- slaperigheid
- abnormale vel sensasies (tinteling of kielie of jeuk of brand)
- probleme met koördinasie en spraak (ataksie)
- geen reuk- of smaakgevoel of smaak word beïnvloed nie
- verergering van bestaande epilepsie (aanvalle)
- vermindering van vroulike vrugbaarheid
- vaginale bloeding
- teer borste.

As u enige newe -effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u u dokter of apteker daarvan in kennis stel.

Rapportering van newe -effekte

Praat met u dokter of apteker of verpleegkundige as u newe -effekte kry. U kan ook newe -effekte by die SAHPRA aanmeld via die “6.04 ongewenste geneesmiddelreaksie - aanmeldingsvorm”, aanlyn gevind in die publikasies van SAHPRA: https://www.sahpra.org.za/Publikasies/Indeks/8.

Deur newe -effekte te rapporteer, kan u help om meer inligting te verskaf oor die veiligheid van **COLCIBRA**.

5. Hoe om COLCIBRA te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of benede 25 °C.

Moenie hierdie medisyne gebruik na die vervaldatum op die karton nie.

Stuur alle ongebruikte medisyne terug aan u apteker.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat COLCIBRA bevat

Die aktiewe bestanddeel is selekoksib.

1 Kapsule bevat 100 mg of 200 mg selekoksib.

Die ander bestanddele is:

Laktose monohidraat

Povidien

Kolloïdale anhidriese silika

Natrium Louriel Sulfaat

Krosskarmellose Natrium

Magnesium Stearaat

Gesuiwerde Water

Hoe COLCIBRA lyk en die inhoud van die verpakking

COLCIBRA 100 mg:

Ondeursigtige, wit tot naaswit harde gelatienkapsules met 'CC' op die dop en '100' op die omhulsel van die kapsules met swart ink, bevattende wit tot naaswit korrelpoeier en/of saamgeperste massa.

COLCIBRA 200 mg:

Ondeursigtige, wit tot naaswit harde gelatienkapsules met 'CC' op die dop en '200' op die omhulsel van die kapsules met swart ink, bevattende wit tot naaswit korrelpoeier en/of saamgeperste massa.

COLCIBRA kapsules word verpak in Aclar/PVC/Alu stulpverpakkings. Stulpstroke wat 30 of 60 bevat word in ‘n karton verpak saam met ‘n voubiljet.

Houer van die Sertifikaat van Registrasie

Ranbaxy Pharmaceuticals (Edms) Bpk

Lautreweg 14, Stomill, Uitb 1

Roodepoort, 1724

Hierdie pamflet is laas hersien in

Desember 2021

Registrasienommer

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