SCHEDULING STATUS

S2

DICLOFENAC 50 mg CLICKS, tablets

Diclofenac sodium

Sugar free

Read all of this leaflet carefully because it contains important information for you.

DICLOFENAC 50 mg CLICKS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DICLOFENAC 50 mg CLICKS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DICLOFENAC 50 mg CLICKS with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What DICLOFENAC 50 mg CLICKS is and what it is used for
2. What you need to know before you take DICLOFENAC 50 mg CLICKS
3. How to take DICLOFENAC 50 mg CLICKS
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1. What DICLOFENAC 50 mg CLICKS is and what it is used for

DICLOFENAC 50 mg CLICKS, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

DICLOFENAC 50 mg CLICKS is used for the symptomatic and supportive treatment of:

- mild to moderate pain of inflammatory origin,

- fever,
- emergency treatment of gout attacks.

2. What you need to know before you take DICLOFENAC 50 mg CLICKS

Do not take DICLOFENAC 50 mg CLICKS

- if you are hypersensitive (allergic) to diclofenac or any of the other ingredients of DICLOFENAC 50 mg CLICKS (listed in section 6),
- if you think you may have reacted to any other NSAID (e.g. aspirin, ibuprofen) with sensitivity reactions like asthma, acute rhinitis (runny nose) and urticaria (itchy skin rash),
- if you have had gastro-intestinal (stomach or duodenal) ulcers,
- if you have had bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces) after you have taken other NSAIDs,
- if you have previously had medical problems with your kidney or liver,
- if you have had a history of heart disease, stroke and / or circulation issues,
- if you are pregnant, do not use NSAIDs at 20 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.

Warnings and precautions

Special care should be taken with DICLOFENAC 50 mg CLICKS

- if you have had history of gastro-intestinal problems including bleeding or ulceration, especially if you are an elderly person,
- if you have had history of gastro-intestinal disorders including inflammatory bowel diseases such as Crohn’s disease or ulcerative colitis, gastro-oesophageal reflux diseases or angiodysplasia (an abnormality with blood vessels of the gastrointestinal tract),
- if you develop symptoms of bleeding or ulceration during therapy (see section 4), or whether your therapy includes increasing doses of DICLOFENAC 50 mg CLICKS,

- if you are suffering from haemophilia or platelet disorders, or when you are on anti-coagulants,
- if you have previously had an allergic medical reaction after the use of aspirin,
- when you are using methotrexate and DICLOFENAC 50 mg CLICKS simultaneously, serious allergic reactions can occur,
- if you have pre-existing cardiovascular disease, or possess risk factors for developing cardiovascular disease (hypertension, hyperlipidaemia, diabetes mellitus and smoking),
- if you have had kidney, liver, or any prior water retention or oedema problems,
- if you develop allergic reactions which cause skin rash, itching, blistering, painful red areas or mucosal lesions (abnormal alteration of the mouth surface),
- tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.

Children

Do not give DICLOFENAC 50 mg CLICKS to small children as it is unlikely to be safe.

Other medicines and DICLOFENAC 50 mg CLICKS

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

The concomitant use of DICLOFENAC 50 mg CLICKS and:

- methotrexate may cause serious reactions,
- lithium causes increased concentrations of lithium in your blood,
- other NSAIDs (ibuprofen and aspirin) can intensify stomach or bowel side effects,
- corticosteroids increase the risk of gastrointestinal adverse reactions,
- anticoagulants (blood thinning tablets like warfarin) may cause enhanced risk of bleeding,
- selective serotonin reuptake inhibitors (SSRIs) and anti-platelet medicines increases the risk

of gastrointestinal bleeding,

- patients who have had an allergic-type reaction after taking aspirin are also sensitive to other NSAIDs (see section 2).

DICLOFENAC 50 mg CLICKS with food

It is advised to take medication after meals (see section 3).

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 health care provider for advice before taking DICLOFENAC 50 mg CLICKS.

The use of DICLOFENAC 50 mg CLICKS in the third trimester of pregnancy may harm unborn child as well as delay and prolong labour.

No data on the influence of fertility is available.

Driving and using machines

DICLOFENAC 50 mg CLICKS may cause dizziness or tiredness, which could have a moderate influence on the ability to perform or execute tasks.

It is not always possible to predict to what extent DICLOFENAC 50 mg CLICKS may interfere with your daily activities. You should ensure that you express caution in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which DICLOFENAC 50 mg CLICKS affects you.

3. How to take DICLOFENAC 50 mg CLICKS

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

Always take DICLOFENAC 50 mg CLICKS exactly as described in this leaflet or as your doctor or pharmacist told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose is 75 mg to 150 mg daily divided into two to three doses for a treatment period of 3 to 5 days. Swallow the tablets whole with a glass of water after food.

Use of DICLOFENAC 50 mg CLICKS should be limited to the lowest effective dose for the shortest possible duration of treatment in order to minimize the potential risk for cardiovascular or gastrointestinal adverse events (see section 2).

For the relief of pain:

Take a maximum daily dose of 75 mg after meals (for a maximum treatment period of 5 days).

For the management of an acute gout attack:

Take 50 mg tablets three times daily after meals (maximum daily dosage of 150 mg) for a maximum treatment period of 3 days.

DICLOFENAC 50 mg CLICKS is not recommended for use in small children.

If you take more DICLOFENAC 50 mg CLICKS than you should

Overdosage can cause increased severity of side effects (see section 4).

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

If you forget to take DICLOFENAC 50 mg CLICKS

Do not take a double dose to make up for forgotten individual dose. Take the dose as soon as you remember.

4. Possible side effects

DICLOFENAC 50 mg CLICKS can have side effects.

Not all side effects reported for DICLOFENAC 50 mg CLICKS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while DICLOFENAC 50 mg CLICKS, please consult your health care provider for advice.

If any of the following happens, stop taking DICLOFENAC 50 mg CLICKS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure),
- Signs of an early stroke are indicative of sudden numbness or weakness in one side of the body particularly of the face, arm or leg, severe headaches,
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces / stools,
- Sudden and severe abdominal pain, nausea and vomiting, which can be indicative of perforation (a split in the stomach or intestines) or ulcerative colitis (inflammatory bowel disease),
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, swollen face, lips, hands or fingers.

These are all very serious side effects. If you have them, you may have had a serious reaction to DICLOFENAC 50 mg CLICKS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- stomach pain,
- nausea and vomiting (feeling sick),
- changes in bowel frequency leading to diarrhoea or constipation,
- heartburn or indigestion,
- flatulence (bloating),
- loss of appetite,

- headache,
- dizziness or light-headedness,
- nervousness,
- skin rash and itching,
- raised levels of liver enzymes in the blood.

Less frequent side effects:

- Fast or irregular heart beat (palpitations),
- chest pain,
- breathlessness when lying down,
- swelling of the feet or legs,
- stomach ulcers or bleeding,
- lower gut disorders (inflammation, irritation or swelling of the stomach lining), constipation,
- abdominal pain that radiates to your back (pancreatitis),
- bleeding in the digestive tract (melaena or haematemesis),
- disturbance of vision (blurred or double vision),
- impaired hearing or ringing in the ears,
- tiredness or drowsiness, bruising,
- change of taste sensation,
- mouth ulcers or of increased extent (ulcerative stomatitis),
- severe skin rash and itching, purpura (blood spots on skin), sensitivity for sun exposure,
- kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.
- hypertension (high blood pressure),
- hepatitis with or without jaundice (inflammation of the liver which may cause yellowing of the skin or eyes),
- fulminant hepatitis (severe liver function impairment, which causes liver failure),
- thrombocytopenia (low level of platelets in the blood),
- leucopoenia (a reduction in the number of white cells in the blood),

- haemolytic anaemia (a disorder in which red blood cells are destroyed faster than they can be made),
- aplastic anaemia (deficiency of all types of blood cells),
- agranulocytosis (blood disorder that decreases the number of white blood cells in the circulating blood).

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 DICLOFENAC 50 mg CLICKS.

5. How to store DICLOFENAC 50 mg CLICKS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C,
- protect from light and moisture,
- do not use after the expiry date stated on the label / carton / bottle,
- do not dispose of unused medicine in drains or sewerage systems (e.g. toilets),
- return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What DICLOFENAC 50 mg CLICKS contains

The active substance is diclofenac sodium.

The other ingredients are acryl EZE yellow (93A82339), calcium sulphate dihydrate, docusate sodium, magnesium stearate, maize starch, HPMC (Hydroxy propyl methyl cellulose) E-5, sodium starch glycolate, polyethylene glycol 600.

What DICLOFENAC 50 mg CLICKS looks like and contents of the pack

Tan coloured, round, biconvex, enteric (film) coated tablets packed in white polypropylene securitainers with LDPE closures and PVC film / printed aluminium foil blister packs of 9 tablets per pack.

Holder of Certificate of Registration

Adcock Ingram Limited

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