1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

DICLO-FLAM BLACKCURRANT 50,0 mg dispersible tablets

46,5 mg of diclofenac free acid,

equivalent to 50,0 mg of diclofenac sodium

Contains sweetener: Saccharin sodium 0,26 mg

Sugar free

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

DICLO-FLAM BLACKCURRANT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DICLO-FLAM BLACKCURRANT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DICLO-FLAM BLACKCURRANT 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 after 3 days.

What is in this leaflet

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

1. What DICLO-FLAM BLACKCURRANT is and what it is used for

DICLO-FLAM BLACKCURRANT belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

DICLO-FLAM BLACKCURRANT is indicated for the emergency treatment of attacks of severe pain, swelling, warmth, redness and tenderness in one or more joints (acute gout attacks). With a maximum daily dose of 150 mg for a maximum treatment period of 3 days.

2. What you need to know before you take DICLO-FLAM BLACKCURRANT

Do not take DICLO-FLAM BLACKCURRANT

- if you are hypersensitive (allergic) to diclofenac sodium or any of the other ingredients of DICLO-FLAM BLACKCURRANT (listed in section 6).
- if you are allergic to aspirin, ibuprofen or any other NSAID. Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- if you have asthma and experience attacks of asthma after taking acetylsalicylic acid or other NSAIDs.
- if you have now, or have ever had, a stomach (gastric) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces).
- if you have had stomach or bowel problems after you have taken other NSAIDs.
- if you have kidney or liver failure.
- if you have heart failure, established heart disease and/or cerebrovascular disease, e.g. if you have had a heart attack or stroke.

- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria).
- if you are pregnant and you are already at 20 weeks or later in your pregnancy, as DICLO-FLAM BLACKCURRANT may cause problems in your unborn baby.
- if you are breastfeeding your baby.

Warnings and precautions

Take special care with DICLO-FLAM BLACKCURRANT:

- if you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease (inflammatory diseases), hiatus hernia, gastro-oesophageal reflux disease (reflux of gastric contents into the oesophagus), angiodysplasia (a small vascular malformation of the gut) as these conditions may be exacerbated.
- if you have or have had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen, and report them at once to your doctor. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.
- if you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- if you have kidney or liver problems, or if you are elderly.
- if you have a pre-existing disorders of blood coagulation.
- if you suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- if you ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract.

- if you have an infection since symptoms such as fever and inflammation may be masked. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- if you have heart problems, chest pain or if you had a stroke or you think you might be at risk of these conditions (for example, if you have high blood pressure, high blood sugar levels, high amounts of fat in the blood or are a smoker). There is an increased risk of heart attack or stroke when you are taking DICLO-FLAM BLACKCURRANT. Always follow the doctor's instructions on how much to take and how long to take it for.
- if you, at any time while taking DICLO-FLAM BLACKCURRANT, experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness or slurring of speech, contact your doctor immediately.
- if you have Systemic Lupus Erythematosus (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition.
- if you have serious skin reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS). DICLO-FLAM BLACKCURRANT should be discontinued immediately at the first appearance of any type of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity. You should also contact your doctor as soon as possible.
- if you have any allergic reaction including chest pain, which can be a sign of a potentially serious allergic reaction (Kounis syndrome).
- if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking DICLO-FLAM BLACKCURRANT, as DICLO-FLAM BLACKCURRANT can sometimes worsen wound healing in your gut after surgery.

- if you are pregnant, do not use DICLO-FLAM BLACKCURRANT at 20 weeks or later in pregnancy. DICLO-FLAM BLACKCURRANT may cause kidney problems in your unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop. Complications can occur with low levels of this fluid.

Children and adolescents

DICLO-FLAM BLACKCURRANT is not suitable for children aged under 14 years.

Other medicines and DICLO-FLAM BLACKCURRANT

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

Tell your doctor if you are taking any of the following:

- Medicines to treat diabetes.
- Anti-platelets and anticoagulants (blood thinning tablets), such as aspirin, heparin or warfarin.
- Diuretics (water tablets).
- Lithium (a medicine used to treat depression).
- Methotrexate (a medicine used for the treatment of some inflammatory diseases and some cancers).
- Ciclosporin and tacrolimus (a medicine used to treat some inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone antibiotics (a medicine for infections).
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen.
- Mifepristone (a medicine used to terminate pregnancy).

- Cardiac glycosides (for example digoxin), used to treat heart problems.
- Selective serotonin reuptake inhibitors (SSRIs (used to treat depression)).
- Oral Corticosteroids (an anti-inflammatory medicine).
- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Sulfinpyrazone (a medicine used to treat gout).
- Phenytoin (a medicine used to treat seizures).
- Colestipol/cholestyramine (a medicine used to lower cholesterol).

DICLO-FLAM BLACKCURRANT with food and drink

DICLO-FLAM BLACKCURRANT tablets should preferably be taken on an empty stomach.

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 provider for advice before taking this medicine.

Pregnancy

You should not take DICLO-FLAM BLACKCURRANT if you are already at 20 weeks or later in your pregnancy.

DICLO-FLAM BLACKCURRANT must not be taken at 20 weeks or later in your pregnancy since it may cause major heart, lung and kidney disorders in the unborn child. If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions delaying the onset of delivery.

Breastfeeding

You should not take DICLO-FLAM BLACKCURRANT if you are breastfeeding your baby.

Fertility

Taking DICLO-FLAM BLACKCURRANT tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Driving and using machines

DICLO-FLAM BLACKCURRANT may cause dizziness and visual disturbances which may affect your ability to perform skilled tasks, if you are affected, you should not drive or operate machinery.

It is not always possible to predict to what extent DICLO-FLAM BLACKCURRANT may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DICLO-FLAM BLACKCURRANT affects you (see section 4).

3. How to take DICLO-FLAM BLACKCURRANT

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

Always take DICLO-FLAM BLACKCURRANT exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

Adults

The usual dose of DICLO-FLAM BLACKCURRANT is

dissolve one tablet in water three times a day for acute gout attacks.

The recommended initial daily dose is 100 mg (2 tablets) to 150 mg (3 tablets).

In milder cases 50 mg (1 tablet) to 100 mg (2 tablets) daily is usually sufficient.

The total daily dosage should generally be divided into 2 to 3 separate doses.

The maximum daily dose is 150 mg for a maximum treatment period of 3 days (three DICLO-FLAM BLACKCURRANT dispersible tablets in divided doses).

Adolescents (aged 14 years or over)

The usual dose of DICLO-FLAM BLACKCURRANT is a daily dose of 50 mg (1 tablet) to 100 mg (2 tablets).

The total daily dose should generally be divided in 2 to 3 doses.

The maximum daily dose of 150 mg (3 tablets) should not be exceeded.

DICLO-FLAM BLACKCURRANT tablets should be dropped into a glass of water and the liquid stirred to aid dispersion before swallowing. Since a proportion of DICLO-FLAM BLACKCURRANT may remain in the glass after swallowing, it is advisable to rinse the glass with a small amount of water and to swallow again.

The tablets must not be divided or chewed.

If you have the impression that the effect of DICLO-FLAM BLACKCURRANT is too strong or too weak, tell your doctor or pharmacist.

If you take more DICLO-FLAM BLACKCURRANT than you should

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

Symptoms of an overdose can include: headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, rarely diarrhoea, disorientation, excitation,

coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you forget to take DICLO-FLAM BLACKCURRANT

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

4. Possible side effects

DICLO-FLAM BLACKCURRANT can have side effects.

Not all side effects reported for DICLO-FLAM BLACKCURRANT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking DICLO-FLAM BLACKCURRANT, please consult your healthcare provider for advice.

If any of the following happens, stop taking DICLO-FLAM BLACKCURRANT 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,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or toxic epidermal, necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to DICLO-FLAM BLACKCURRANT. 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:

- sudden and crushing chest pain (signs of myocardial infarction, heart attack or Kounis syndrome),
- heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day),
- fast or irregular heartbeat (palpitations),
- sudden weakness or numbness in the face, arm or leg especially on one side of the body, sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke,
- high blood pressure (hypertension), low blood pressure, symptoms of which may include faintness, giddiness or light headedness (hypotension),
- lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease),
- inflammation of the pancreas (pancreatitis),
- stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick),
- vomiting blood (haematemesis), black, tarry faeces or stools (melaena),
- diarrhoea containing blood or rectal bleeding (diarrhoea haemorrhagic),
- any sign of ulcers or bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces,
- kidney failure, kidney pain or inflammation of the kidneys,
- liver disorders including liver failure, presence of blood or protein in the urine,
- an unexpected change in the amount of urine produced and/or its appearance,
- yellowing of your skin or the whites of your eyes (jaundice),
- wheezing or shortness of breath (bronchospasm),

- breathlessness, coughing and a tightness across the chest (asthma),
- inflammation of the lung (pneumonitis),
- inflammation of blood vessels (vasculitis),
- inflammation of the lining of the brain with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation (meningitis),
- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with DICLO-FLAM BLACKCURRANT and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain,
- if you notice that you are bruising more easily than usual or have frequent sore throats or infections.

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:

- stomach pain, heartburn, nausea, vomiting, diarrhoea, constipation, indigestion, wind, burping, loss of appetite,
- inflammation, irritation or swelling of the stomach lining (gastritis),
- headache, dizziness, nervousness,
- vertigo,
- raised levels of liver enzymes in the blood.

Less frequent side effects:

- drowsiness, tiredness (somnolence),
- fluid retention, symptoms of which include swollen ankles (oedema),
- liver function disorders,
- visual disturbances such as blurred or double vision,

- hearing impairment, tinnitus (ringing in the ears),
- sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation, loss of memory, fits,
- confusion, hallucinations, malaise (general feeling of discomfort),
- tingling or numbness in the fingers,
- tremor, taste changes,
- inflammation of the tongue (glossitis), mouth ulcers (aphthous), inflammation of the inside of the mouth or lips (stomatitis),
- blood disorders (including anaemia),
- photosensitivity (increased sensitivity to sunlight),
- hair loss,
- loss of male sexual ability (impotence).

Side effects with an unknown frequency:

- inflammation of the nerves in the eye (optic neuritis).

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. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of DICLO-FLAM BLACKCURRANT.

5. How to store DICLO-FLAM BLACKCURRANT

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep the blister in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 DICLO-FLAM BLACKCURRANT contains

The active substance is 46,5 mg of diclofenac free acid, equivalent to 50,0 mg of diclofenac sodium.

The other ingredients are blackcurrant flavour, croscarmellose sodium, glycerol distearate, microcrystalline cellulose, purified talc, saccharin sodium, sodium starch glycolate.

Contains sweetener: Saccharin sodium 0,26 mg

Sugar free

What DICLO-FLAM BLACKCURRANT looks like and contents of the pack

DICLO-FLAM BLACKCURRANT is a white to off-white, diamond-shaped biconvex tablet, bisected on one side, with a blackcurrant odour.

9 dispersible tablets are packed in a clear polyvinylchloride, polyethylene and polyvinylidene chloride film sealed with an aluminium foil backing. One blister strip is packed into an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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