PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

FLENODIC 25 tablets.

Contains sugar. Lactose monohydrate 65 mg per tablet.

FLENODIC 100 SR tablets.

Sugar free

Diclofenac sodium

Read all of this leaflet carefully before you start taking FLENODIC

- 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.
- FLENODIC has been prescribed for you personally and you should not share your medication with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FLENODIC is and what it is used for

2. What you need to know before you take FLENODIC

3. How to take FLENODIC

4. Possible side effects

5. How to store FLENODIC

6. Contents of the pack and other information

1. What FLENODIC is and what it is used for

Diclofenac sodium, the active ingredient in FLENODIC 25 and FLENODIC 100 SR, is one of a group of

medicines called non-steroidal medicine with anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

FLENODIC tablets relieve pain, reduces inflammation and swelling in conditions affecting the muscles, joints and tendons including:

- Rheumatic arthritis, osteoarthrosis and ankylosing spondylitis (form of spinal arthritis).
- Post-operative and post -traumatic pain associated with inflammation and swelling.
- They are also used to treat pain and inflammation associated with dental and minor surgery.
- Relieve of dysmenorrhoea (period pains).

2. What you need to know before you take FLENODIC

Do not take FLENODIC if:

- you are allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of FLENODIC tablets (these are listed under section 6)
- you have now, or ever had, a duodenal (peptic) ulcer or bleeding in the digestive tract, this bleeding may result in vomiting of blood, bleeding when emptying bowels, fresh blood or black blood in faeces
- you ever had asthma, seasonal allergic rhinitis or other chronic pulmonary disease
- you are breastfeeding you baby
- you are pregnant
- you have porphyria
- you have high blood pressure, high cholesterol or angina
- you have any heart problems or if you had a stroke
- you have had stomach or bowel problems after you have taken other NSAIDs

Warnings and precautions

If you are taking FLENODIC for longer than the recommended time or at higher than recommended doses, you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4)

Tell your doctor or healthcare provider before taking FLENODIC if:

- you have liver or kidney problems
- you have heart problems
- you have high blood pressure
- you have high cholesterol
- you are smoking
- you have diabetes
- you have angina, or if you ever had a stroke or if you think you might be a risk
- you are an elderly
- you suffer from any blood or bleeding disorders
- you suffer from stomach or duodenal ulcers
- you suffer from any stomach or bowl disorders including ulcerative colitis, Crohn's disease or gastro-oesophageal reflux diseases
- you have any serious skin reaction
- you have Systemic Lupus Erythematosus SLE (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition
- you develop flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- you ever had asthma, seasonal allergic reactions, swelling of the nasal mucosa, chronic pulmonary disease or chronic infections of the respiratory tract

Children

Not recommended for children.

Other medicines and FLENODIC

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

- if you are using any other NSAIDs like ibuprofen, or other cyclo-oxygenaseo-2 inhibitors like aspirin
- antihypertensive medicines and diuretics (water tablets)
- lithium (used to treat some mental problems)
- ciclosporin and tacrolimus (used to treat some inflammatory diseases)
- any oral steroids (an anti-inflammatory drug)
- anticoagulants (blood thinning tablets)
- medicines to treat diabetes
- methotrexate (for the treatment of some inflammatory diseases and some cancers)
- quinolone antibiotics (for infections)
- phenytoin (a medicine used to treat seizures)
- colestipol and cholestyramine (lower cholesterol)
- cardiac glycosides (used to treat heart problems)
- mifepristone (used to terminate pregnancy)
- selective reuptake inhibitors (used to treat depression)

FLENODIC with food and alcohol

FLENODIC should be taken with or after food.

Pregnancy, breastfeeding and fertility

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

Do not take FLENODIC if you are pregnant.

Do not breastfeed your infant.

If you are trying to conceive, the dose of FLENODIC should be kept as low and duration of treatment as short as possible.

Driving and using machines

You may feel dizzy, tired or sleepy or if you have difficulty with your eyesight do not drive or operate machinery.

It is not always possible to predict to what extent FLENODIC may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which FLENODIC affects you.

3. How to take FLENODIC

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

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

Take tablets with or after food. Swallow tablets whole with a glass of water.

Do not crush or chew the tablets.

FLENODIC 25 Tablets

The usual dose is 1 tablet, 25 mg diclofenac, two to three times daily in divided doses.

FLENODIC 100 SR Tablets

The usual dose is 1 tablet daily.

Children

Not recommended for children.

If you take more FLENODIC than you should

See section 4 Side effects below.

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

If you forget to take FLENODIC

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

4. Possible side effects

FLENODIC can have side effects.

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

If any of the following happens, stop taking / using FLENODIC 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 ore breathing,
- rash or itching,

- fainting.
- FLENODIC, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood. This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLENODIC. 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
- angina
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- changes in the way your heart beats, for example, if you notice it beating faster
- 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
- yellowing of your skin or the whites of your eyes
- signs of recurrent infections such as fever or sore throat
- Stevens Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals)
- less urine than is normal to you

- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with FLENODIC and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

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:

- nausea
- vomiting
- diarrhoea
- abdominal pain
- flatulence
- anorexia
- abdominal cramps and discomfort
- local irritation
- headache
- dizziness
- feeling of off balance
- liver function abnormal

Less frequent side effects:

- inflammation of the lining of the stomach
- bleeding in the gastrointestinal tract
- stomach ulcers with or without a rupture in the gastrointestinal tract
- vomiting of blood
- bright red or black blood in stool
- inflammation of the inner lining of the colon
- constipation
- small sores in the inside of the mouth
- inflammation of the mouth
- inflammation of the pancreas
- loss of blood because of the vomiting of blood or the loss of blood after a stool
- blood disorders such as deficiency of red blood cells, low number of platelets, a low level of white blood cells in the blood, which can interfere with the ability to fight infection
- a rare condition in which the body stops producing enough new blood cells, an abnormally low count of a type of white blood cell
- a high level of disease-fighting white blood cells known as eosinophils in the blood, a disorder in which red blood cells are destroyed faster than they can be made
- asthma, inflammation of lung tissue
- disorientation
- depression
- nightmares
- irritability
- pins and needles
- anxiety
- impaired concentration

- tremor
- sweating
- memory disturbance
- fits, an illness characterised by serous inflammation of the linings of the brain (i.e., meninges)
- taste alterations, tiredness
- sleeplessness or sleepiness
- blurred vision, double vision
- changes in the colour, damage to the optic nerve
- loss of hearing, ringing of ears
- high/low blood pressure fluctuations, inflammation of blood vessels
- liver disorders including liver failure and liver, acute toxic injury of the liver, increase in liver enzymes
- Lyell's syndrome and other skin rashes which may be made worse by exposure to other skin rashes which may be made worse by exposure to sunlight
- loss of hair, hives
- kidney failure, presence of blood or protein in the urine, is order of the kidneys in which all or part of the renal papillae die
- kidney disorder that causes the body to excrete too much protein in the urine
- kidney disorder in which the spaces between the kidney tubules become swollen (inflamed), inflammation of the bladder
- impotence
- swelling and swelling of your lower legs and arms

Side effects with unknown frequency

- occurs when blood flow to part of the large intestine (colon) is temporarily reduced, usually due to

constriction of the blood vessels supplying the colon or lower flow of blood through the vessels due to low pressures

- confusion, hallucinations, malaise (general feeling of discomfort), disturbances of sensation
- inflammation of the nerves in the eye
- symptoms such as chest pain (relating to reduced blood flow to the heart) caused by an allergic reaction or a strong immune reaction to a drug or other substance.

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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FLENODIC.

5. How to store FLENODIC

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light and moisture

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 FLENODIC contains

FLENODIC 25 Tablets:

The active substance is 25 mg diclofenac sodium.

The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate,

methylcellulose and stearic acid.

The sub coating is Instacoat universal transparent A05R00946.

The enteric coating are D&C yellow no.10, polyethylene glycol 6000, Idalacol lake sunset yellow exspl (L70), titanium dioxide, ferric oxide, methacrylic acid, talc.

FLENODIC 100 SR Tablets:

The active substance is 100 mg diclofenac sodium.

The other ingredients are dextrates, hydroxyethyl cellulose (250 HHX), magnesium stearate, and microcrystalline cellulose (PH 102).

The film-coating is Instacoat Universal Pink (A05R00870)

What FLENODIC looks like and contents of the pack

FLENODIC 25 tablets are mustard yellow coloured, round bevelled edge, biconvex, enteric coated tablets plain on both the sides.

FLENODIC 100 SR tablets are round, pink, biconvex tablet, bevel edged, plain on both sides.

FLENODIC 25 tablets are packaged in white HDPE round bottles with HDPE screw cap with induction sealing liner with pack sizes of 15, 42, 84, 100 and 500. Or white opaque PE zip lock patient ready packs with pack sizes of 15 and 84.

FLENODIC 100 SR are packaged in white Alu/PVC blister packs of 10 blister per strip, and 3 blister strips per outer carton (pack sizes of 30).

Not all pack sizes may be marketed at the same time.

Holder of Certificate of registration

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