

SLOW DICLOFENAC TABLETS

Diclofenac Sodium (100 mg)

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What *SLOW DICLOFENAC TABLETS* is used for

SLOW DICLOFENAC TABLETS is used to treat:

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis (systemic inflammatory disorder that affects joints); ankylosing spondylitis (chronic inflammatory disease of the skeleton); osteoarthritis (degenerative joint disease) and spondylarthritis (inflammation of the joint).
- Painful syndromes of the spinal column.
- Non-articular rheumatism. (musculoskeletal aches and pains which do not arise from joints)
- Painful posttraumatic and post-operative inflammation and swelling.

How *SLOW DICLOFENAC TABLETS* works

Slow Diclofenac tablet contains a substance called Diclofenac. Diclofenac belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat pain and reduce inflammation (swelling and redness). It works by inhibiting prostaglandin synthesis which has major role in pain and inflammation.

Before you use *SLOW DICLOFENAC TABLETS*

- *When you must not use it*

Do not use *SLOW DICLOFENAC TABLETS* if you are allergic (hypersensitive) to:

- diclofenac (the active ingredient in *SLOW DICLOFENAC TABLETS*) or any of the other ingredients listed at the end of this leaflet
- other medicines containing diclofenac
- aspirin
- any other NSAID

Do not take *SLOW DICLOFENAC TABLETS* if you have:

- Peptic ulcer.
- If you have had asthma, rhinitis (Inflammation of the nasal mucous membrane), urticaria (itching or hives) and the symptoms become worsen caused by Aspirin or NSAIDs.

Pregnancy and lactation

Do not take *SLOW DICLOFENAC TABLETS* if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking *SLOW DICLOFENAC TABLETS*, stop taking it immediately and contact your doctor. Your doctor can discuss with you the risks of using it while you are pregnant.

Do not take *SLOW DICLOFENAC TABLETS* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

Tell your doctor if you have any of the following health problems / medical conditions:

- past or present heart problems or high blood pressure
- a past history of ulcers and perforation (stomach or intestinal)
- gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort

- heartburn after taking anti-inflammatory medicines in the past
- diseases of the bowel or inflammation of the intestinal tract (Crohn's disease) or colon (ulcerative colitis)
- liver or kidney problems
- bleeding disorders or other blood disorders (e.g. anaemia)
- swollen feet, fluid retention and oedema
- if you are taking diuretic "water pills"
- if you are recovering from major surgical operation.
- if you are elderly
- Diclofenac may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.
- as with other non-steroidal anti-inflammatory drugs, allergic reactions, including anaphylactic / anaphylactoid reactions, can occur also without earlier exposure to the medication.
- if you have risk of thrombosis, e.g. stroke.

Your doctor may want to take special precautions if you have any of the above conditions.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Some medicines when taken with Slow Diclofenac tablet may interfere with each other. These include:

- other anti-inflammatory medicines, e.g. aspirin, other NSAIDs
- warfarin or other "blood thinners" (medicines used to prevent blood clotting)

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- digoxin (a medicine for heart problems)
- lithium a medicine used for psychiatric disease.
- diuretics (medicines used to increase the amount of urine)
- other corticosteroids (medicines used to provide relief for inflamed areas of the body)
- medicines used to treat diabetes
- methotrexate (a medicine used to treat arthritis and some cancers)
- cyclosporin (a medicine used in patients who have received organ transplants)

You may need to take different amounts of your medicines or to take different medicines while you are using *SLOW DICLOFENAC TABLETS*.

Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start using this medicine.

How to use *SLOW DICLOFENAC TABLETS*

– How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Take *SLOW DICLOFENAC TABLET* one tablet per day.

Do not break or do not chew *SLOW DICLOFENAC TABLET*

Do not use *SLOW DICLOFENAC TABLET* in Children.

– When to use it

Use as directed by your doctor or pharmacist.

SLOW DICLOFENAC TABLET should be taken whole with liquid, preferably with meal.

If you have more pronounced symptoms in the night or on the morning, you can take it in the evening or as directed by your doctor.

– How long to use it

Continue taking *SLOW DICLOFENAC TABLETS* for as long as your doctor recommends.

Keep shortest possible duration of treatment.

– If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

– If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause acute poisoning and need medical treatment. Symptoms include convulsions (fits), hypotension (low blood pressure) and respiratory depression. In cases of significant poisoning acute renal failure are possible.

While you are using it

– Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *SLOW DICLOFENAC TABLETS*.

Tell your doctor immediately if you become pregnant while taking this medication. Your doctor can discuss with you the risks of using it while you are pregnant.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to check your kidneys, liver and blood from time to time to help prevent unwanted side effects.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are using *SLOW DICLOFENAC TABLETS*.

– Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *SLOW DICLOFENAC TABLETS* to anyone else, even if they have the same symptoms or condition as you.

Do not take any of the following medicines while you are using *SLOW DICLOFENAC TABLETS* without first telling your doctor:

- aspirin
- other medicines containing diclofenac
- any other NSAID medicine

If you take these medicines together with *SLOW DICLOFENAC TABLETS*, they may cause unwanted side effects.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

– Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sense of dizziness or

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other neurological disturbances, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *SLOW DICLOFENAC TABLETS* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- Upper abdominal pain, other gastrointestinal disorders such as nausea (feeling sick), vomiting (being sick), diarrhea, gastrointestinal bleeding, peptic ulcer, lower gut disorders such as non-specific haemorrhagic inflammation of colon (haemorrhagic colitis) and exacerbation of ulcers in colon (ulcerative colitis).
- Headache, dizziness or spinning of head, sleepiness, disturbances of sensation or vision such as blurred vision, double vision, ringing noise in ears, difficulty sleeping, irritability, fits.
- Skin rashes, a serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome), itching, "nettle" rash or hives, a serious reaction causing swelling of the face or throat, unusual bruising, peeling, scaling, blistering and hair loss.
- Urinary problems (e.g. any change in the usual amount or color of the urine, blood in urine), kidney problems.

- Inflammation of liver (hepatitis) with or without yellowing of the skin/white of the eye (jaundice).
- High platelet count (thrombocytosis), decrease white blood cell count (leucopenia), decrease in hemoglobin (anemia)
- Swelling (edema), hypersensitivity reactions which may include mild symptoms such as itching and/or rash or more severe symptoms such as swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing (anaphylactic reaction).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of *SLOW DICLOFENAC TABLETS*

– Storage

Keep out of the reach and sight of children.

Store below 25 °C.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

– Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

– What it looks like

Pink coloured biconvex, film coated circular tablets plain on both sides.

– Ingredients

Active ingredient(s)
Diclofenac Sodium

Inactive ingredients
Polymer A, Lactose, Polyvinylpyrrolidone, Isopropyl Alcohol, Magnesium Stearate, Talc, Colloidal Silicone Dioxide, Hydroxypropyl Methyl-Cellulose, Polyethylene Glycol 4000, Propylene Glycol, Titanium Dioxide, Lake of Ponceau 4R, Methanol, Methylene Chloride

MAL number: MAL19985471AZ

Manufacturer

LUPIN LABS LTD,
A-28/1, M.I.D.C,
Chikalhana,
Aurangabad – 431 210,
INDIA

Product Registration Holder

PAHANG PHARMACY SDN. BHD
LOT 5979, JALAN TERATAI,
5 1/2 MILE, OFF JALAN MERU
41050 KLANG
SELANGOR.

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