What is in this leaflet

This leaflet answers some of the common questions about DICLOFENAC-GA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DICLOFENAC-GA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may want to read it again.

What DICLOFENAC-GA Tablets are used for

The name of your medicine is DICLOFENAC-GA. It contains the active ingredient diclofenac sodium.

DICLOFENAC-GA is used for treating the symptoms of inflammatory and degenerative forms of rheumatism, rheumatoid arthritis and osteoarthritis. It is also used in conditions where back pain, muscle strains, sprains and tendonitis (e.g. tennis elbow) are observed. It is also used to relieve states of acute or chronic in which there is an inflammatory component, as well as for the symptomatic treatment of dysmenorrhoea (heavy, painful periods).

Your doctor may have prescribed DICLOFENAC-GA for another reason.

Ask your doctor if you have any questions about why DICLOFENAC-GA was prescribed for you.

DICLOFENAC-GA belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It also has analgesic and antipyretic properties.

Diclofenac acts by reducing pain (at rest and on movement), morning stiffness and swelling of the joints associated with rheumatic diseases, as well as improving function.

In addition, it has been shown to relieve pain in dysmenorrhoea.

There is no evidence that DICLOFENAC-GA is addictive.

Before you take DICLOFENAC-GA Tablets

Before you start to take DICLOFENAC-GA Tablets

Tell your doctor if you have any medical conditions, especially the following:

- You have had allergic reactions such as asthma, itchy rash or severe hay fever, swelling of the face, lips, tongue or other parts of the of the body; rash, itching or the hives on the skin.
- After taking aspirin, ibuprofen or any other NSAIDs.
- You suffer from a stomach or intestinal ulcer.
- bleeding from the stomach or bowel (symptoms of which may include blood in your stools or black stools)
- Severe kidney or liver problems.
- Severe heart failure.
- It has passed its expiry date or the packaging appears to have been tampered with.
- You are pregnant or breast feeding, or if there is a possibility that pregnancy may occur.
- Do not use DICLOFENAC-GA during the last three months of the pregnancy as this may affect your baby and may delay labour and birth.

When you must not take DICLOFENAC-GA Tablets

DICLOFENAC-GA tablets should not be used by children. In adults, they should not be taken if:

- You are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description.
Crohn's disease or ulcerative colitis, which are diseases of the bowel
A tendency to bleed or other blood problems such as anaemia
History of haemorrhoids (piles) or irritation of the rectum
Any heart problems, including disease of the heart with shortness of breath, and swelling of the feet or lips due to fluid build-up
Problems with your liver or kidney
A rare liver condition called porphyria
Asthma or any other chronic lung disease that causes difficulty in breathing
Seasonal allergies (e.g. hay fever)
Repeated chest infections
Polyps in the nose
Diabetes
Recent major surgery
High blood pressure

Tell your doctor if you are pregnant or trying to become pregnant or breast feeding
There is not enough information to recommend the use of diclofenac during the first 6 months of pregnancy and it must not be used during the last 3 months. Diclofenac may also reduce fertility and affect your chances of becoming pregnant. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast feeding.
The active ingredient in DICLOFENAC-GA passes into breast milk. Breast feeding is not recommended while you are using this medicine.

Tell your doctor if you are lactose intolerant.
DICLOFENAC-GA tablets contain lactose.

Tell your doctor if you are planning to give this medicine to a child.
Safety and effectiveness in children have not been established.

If you have not told your doctor about any of the above, tell him/her before you start taking DICLOFENAC-GA.

Taking other medicines
Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.
In particular, tell your doctor if you take any of the following:
- Aspirin, salicylates, ibuprofen or other NSAID medicines
- Anticoagulants such as warfarin, medicines used for thinning blood or stop blood clots
- Digoxin, a medicine used to treat heart problems
- Lithium or selective serotonin-reuptake inhibitors (SSRIs), medicines used to treat some types of depression
- Diuretics, also called fluid or water tablets, medicines used to increase the amount of urine
- Ace inhibitors or beta-blockers, medicines used to treat high blood pressure, heart conditions, glaucoma and migraine
- Corticosteroids, medicines such as prednisone or cortisone, which reduce the activity of your immune system
- Antidiabetic agents, for diabetes
- Methotrexate, a medicine used for treatment of rheumatoid arthritis, as well as some types of cancers
- Cyclosporin and tacrolimus, medicines used after organ transplants, as well as in the treatment of rheumatoid arthritis
- Glucocorticoids, a group of anti-inflammatory medicines, used to treat arthritis
- Certain antibiotics called quinolones
- Voriconazole, a medicine used to treat fungal infections
- Sulfapyrazone, a medicine used to treat gout

- Phenytoin, a medicine used in treatment of epilepsy
- Trimethoprim used to treat urinary tract infections

These medicines may be affected by DICLOFENAC-GA, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are currently taking a diuretic and other medicine(s) to help lower blood pressure at the same time. Sometimes diuretics and certain blood pressure lowering drugs are combined in the one product. If you are taking these drug combinations, your doctor may advise a blood test to check your kidney function before you start to take DICLOFENAC-GA.

How to take DICLOFENAC-GA Tablets
The daily dose should generally be prescribed in two or three divided doses. The prescribed dose should be swallowed whole with a glass of water. You may take it with or immediately after food in order to reduce the chance of stomach upset.
The dosage and duration of treatment will be determined for you by your doctor.

Do not chew them.
These tablets have a special coating to stop them dissolving until they have gone through the stomach and into the intestines, where they can start to work. If you chew them, the coating is destroyed.

If you forget to take your dose
Take your dose as soon as you remember, and continue to take it as you would normally.
If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much
Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to accident and emergency at your nearest hospital, if you think that you or anyone else has taken too much DICLOFENAC-GA.

Do this even if there are no signs of discomfort or poisoning.

While you are using DICLOFENAC-GA Tablets

Things you must do

- Always follow your doctor's instructions carefully.
- Keep all your doctor's appointments so that your progress can be checked.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- Inform the surgeon and anaesthetist before going to have a surgery.
- Tell your doctor if you get an infection while using DICLOFENAC-GA.
- Tell your doctor if you become pregnant while taking DICLOFENAC-GA.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking DICLOFENAC-GA.

Things you must not do

- Do not take any of the following medicines while you are taking DICLOFENAC-GA without first telling your doctor:
  - Aspirin (also called ASA or acetylsalicylic acid)
  - Other salicylates
  - Other medicines containing diclofenac
  - Ibuprofen
  - Any other NSAID medicine
  - If you need to take something for headache or fever, it is usually okay to take paracetamol. If you are not sure, your doctor or pharmacist can advise you.
- Do not stop any other form of treatment that your doctor has told you to follow.
- Do not use DICLOFENAC-GA to treat any other complaint unless your doctor says so.
- Do not give this medication to anyone else, even if their symptoms seem similar to yours.

Be careful driving or operating machinery until you know how DICLOFENAC-GA affects you. DICLOFENAC-GA may cause drowsiness, spinning sensation, blurred vision or light-headedness in some people.

Things to be careful of

- heartburn or pain behind or below the breastbone
- altered taste sensation
- abdominal cramps
- flatulence
- anorexia
- rashes
- vertigo
- headache, dizziness
- drowsiness, disorientation, forgetfulness
- feeling depressed, anxious or irritable
- strange or disturbing thoughts or moods
- shakiness, sleeplessness, nightmares
- tingling or numbness of hands or feet
- feeling of fast or irregular heart beat
- unusual weight gain or swelling of ankles or legs due to fluid build-up
- symptoms of sunburn that happen more quickly than usual (redness, itching, swelling, blistering of the lips, eyes, mouth and/or skin)
- blurred or double vision
- buzzing or ringing in the ears, difficulty hearing
- hair loss or thinning
- hypertension (high blood pressure)

These are the more common side effects of DICLOFENAC-GA. Mostly, these are mild and short-lived.

If any of the following happen, stop taking DICLOFENAC-GA, and tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- red or purple skin
- severe pain or tenderness in the stomach, vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea

Side Effects

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

The most common side effects seen in patients taking diclofenac preparations are:

- stomach pain
- nausea, vomiting, diarrhoea, constipation
- sore mouth or tongue
• rash, itching or hives on the skin, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction)
• wheezing, troubled breathing or feelings of tightness in the chest (signs of asthma)
• persistent nausea, loss of appetite, unusual tiredness, vomiting, pain in the upper right abdomen, yellowing of the skin or eyes, dark urine or pale bowel motions
• constant "flu-like" symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy), bleeding or bruising more easily than normal
• development of painful red areas, large blisters, peeling of skin, bleeding lips, eyes, mouth, nose or genitals which may be accompanied by fever and chills, aching muscles and generally feeling unwell
• sudden and severe headache, stiff neck, severe nausea, dizziness, numbness, difficulty in speaking, paralysis, fainting, convulsions/seizures (fits)
• change in the colour or amount of urine passed, blood in the urine, burning feeling when passing urine and frequent need to urinate
• chest pains, which may be a sign of a heart attack
If you feel unusually weak and tired, or notice blood in your faeces, together with severe stomach pain, stop taking the tablets and see your doctor immediately.

These are very serious side effects. You may need urgent medical attention or hospitalisation.
Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After using DICLOFENAC-GA

Storage

Keep DICLOFENAC-GA in the original packaging until you need to take it.
Do not store DICLOFENAC-GA in the bathroom or near a sink.
Do not leave in the car or on window sills.
Store below 25°C in a dry place, out of the reach of children.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return any unused or out of date medicine to your pharmacist.

Product Description

What DICLOFENAC-GA Tablets look like

DICLOFENAC-GA 25 mg: round, brown-yellow film coated tablets. They are available in blister packs of 50 tablets.
DICLOFENAC-GA 50 mg: round, brown-yellow film coated tablets. They are available in blister packs of 50 tablets.

Ingredients

Active Ingredient is diclofenac sodium. DICLOFENAC-GA also contains some inactive ingredients. These are lactose, calcium hydrogen phosphate, microcrystalline cellulose, maize starch, sodium starch glycollate, magnesium stearate, colloidal silicon dioxide, methacrylic acid copolymer, triethyl citrate, talc, titanium dioxide and yellow ferric oxide.