PACKAGE LEAFLET:
Information for the patient

DURILAC

Suppositories – 100 mg
Gel – 1 % - 30 g
Solution for injection – 75 mg / 3 ml
(Diclofenac sodium)

Read this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. WHAT DURILAC IS AND WHAT IT IS USED FOR
Durilac contains the active substance diclofenac sodium, which is a non - steroidal anti - inflammatory drug (NSAID). Its action is based in the inhibition of cyclooxygenases, which participate in the biosynthesis of prostaglandins. Prostaglandins have an important role in the process of pain, inflammation and chills.
Non - steroidal anti - inflammatory drugs inhibit cyclooxygenases - 1 and - 2 (COX - 1 and - 2). Inhibition of COX - 1 is associated with gastrointestinal side effects, while the inhibition of COX - 2 is associated with anti - inflammatory action.
Diclofenac is rapidly absorbed when it is given in the form of rectal suppositories or intramuscular injection. Diclofenac is also absorbed percutaneously. Approximately 99 % of the drug is bound with the plasma proteins. Diclofenac passes in the synovial fluid and in the breast milk. Its plasmatic half life is 1 – 2 hours. It is excreted in the form of glucuronides and sulphates, mainly through urine (65 %) and bile (35 %).
Durilac is used:
- in musculo - skeletal disorders such as rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis;
- in peri - articular disorders such as bursitis and tendinitis;
- in soft - tissue disorders such as sprains and strains;
- in painful conditions such as renal colic, acute gout, dysmenorrhoea;
- after some surgical procedures.

2. BEFORE YOU TAKE DURILAC
Do not take Durilac if you:
- are hypersensitive to diclofenac sodium or to any other excipient of the suppositories, solution for injection or of the dermatological gel;
- have active or preceding peptic ulcer, a history of gastrointestinal bleeding or perforation;
- are hypersensitive to aspirin or to any other nonsteroidal anti – inflammatory drug (which can cause asthma attack, angioedema, urticaria or acute rhinitis);
- suffer from severe cardiac failure;
- have serious hepatic or renal impairment;
- suffer from acute porphyria;
- are pregnant or breast – feeding;
- have disturbances of haemopoiesis with an idiopathic nature.

Durilac should not be used in children.

Additional contraindications only for Durilac – solution for injection
Intravenous use of diclofenac is contraindicated if you:
- have hypovolemia or severe or moderate dehydration;
- are taking other non steroidal anti – inflammatory drugs or anticoagulants;
- have a history of haemorrhagic diathesis, cerebrovascular bleeding or asthma;
- will make a surgical intervention with a high risk of haemorrhage.

Take special care with Durilac
Ask your doctor or pharmacist before you take this drug.

Non - selective nonsteroidal anti - inflammatory drugs are associated with a small increased risk of thrombosis even when used as a short - term treatment in patients with no cardiovascular risk factors. Diclofenac with a dosage of 150 mg daily is associated with an increased risk of thrombosis.

Nonsteroidal anti – inflammatory drugs should be used with caution in patients with hepatic impairment because there is an increased risk of gastro - intestinal bleeding and fluid retention.

Also, nonsteroidal anti – inflammatory drugs should be used with caution in the elderly (increased risk of serious side effects and fatalities) and in patients with hypertension, in allergic disorders, in coagulation disorders and connective - tissue disorders.

In patients with cardiac impairment, caution is required since nonsteroidal anti – inflammatory drugs may impair renal function.

Nonsteroidal anti – inflammatory drugs should be used with caution in patients with renal impairment (the lowest effective doses should be used for the shortest possible duration, and renal function should be monitored).

Patients which suffer of asthma, high temperature, nasal polyps or chronic infections of the respiratory tract and patients with a hipersensitivity to analgesics and to the other nonsteroidal anti - inflammatory drugs are associated with an increased risk of attack of asthma during diclofenac sodium use.

In the case of Durilac – gel, the preparation should be used in undamaged skin and not in wounds. It should not enter in contact with eyes and mucous membranes and also it should not be used by mouth.

Taking other medicines:
Concomitant treatment with other medicines may affect or be affected by Durilac.
Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Durilac if you have been given any other drug during the treatment.

It is particularly important to inform your doctor that you are being treated with:
- ***lithium:*** diclofenac sodium increases plasma concentration of lithium by reducing its renal excretion (increases the risk for toxicity);
- ***digoxin:*** diclofenac sodium increases plasma concentration of digoxin (increases the risk for toxicity);
- ***diuretics:*** the risk of nephrotoxicity by the nonsteroidal anti – inflammatory drugs is increased by diuretics; NSAIDs can antagonize the effect of the diuretics; the risk to hyperkalemia is increased if NSAIDs are administered simultaneously with potassium sparing diuretics;
- ***methotrexate:*** when diclofenac sodium and methotrexate are taken within 24 hours, plasma levels of methotrexate can be increased, thereby increasing its toxicity;
- ***salicylates:*** diclofenac sodium may reduce the salicylates concentration;
- ***corticosteroids and other nonsteroidal anti – inflammatory drugs:*** simultaneous administration of diclofenac with corticosteroids and other nonsteroidal anti – inflammatory drugs (including aspirin in small doses), increases the risk of gastro - intestinal bleeding;
- ***quinolones:*** the risk for convulsions can increase if nonsteroidal anti – inflammatory drugs are administered simultaneously with quinolones;
- ***anticoagulants:*** the anticoagulant effect of coumarins (warfarin) and of phenindions and also the risk for a hemorrhage when it is taken with heparins is increased;
- ***antidepressants:*** increased risk of bleeding when nonsteroidal anti - inflammatory drugs are taken simultaneously with selective inhibitors of serotonin reuptake (SSRI) and venlafaxin;
- ***antidiabetics:*** nonsteroidal anti - inflammatory drugs may increase the effects of sulfonylureas;
- ***ciclosporin:*** plasma concentration of diclofenac is increased by cyclosporin.

Pregnancy and breast - feeding
Durilac should not be used during pregnancy and breast – feeding. Ask the pharmacist or the doctor before taking this drug.

Driving and using machinery
Patients who experience vertigo, visual disturbances, somnolence or other central nervous system disturbances after diclofenac use, should not drive and use machines.

Important informations about some of the excipients of Durilac – solution for injection
Durilac – solution for injection contains sodium sulphite and metabisulphite, which rarely can cause hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE DURILAC
Always take Durilac exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Durilac – suppositories 100 mg:
Adults:
One 100 mg suppository may be given as a once daily treatment, usually at night.
When it is necessary, therapy may be combined with tablets up to a total maximal dose of 150 mg daily of diclofenac in divided doses.

Children:
Durilac – suppositories 100 mg should not be used in children.

Durilac – gel 1 %
Depending on the size of the affected site, apply the gel in a quantity of 2 - 4 g (a quantity between a cherry and a walnut) 3 - 4 times daily and massage it carefully. The duration of the treatment depends on the indication and patient response. It is recommended to review the treatment after 14 days or after 28 days if the gel is used for osteoarthritis. The gel can be used also with other pharmaceutical forms of diclofenac sodium.
Durilac gel should not be used in children.

Durilac – solution for injection 75 mg / 3 ml
The dose is generally one ampoule daily (75 mg), which is injected deeply into the gluteal muscle in the upper and external side. In rare cases, in serious conditions (e.g. colics) can be made two injections, with an interval of a few hours (one on each side). It is possible to combine one ampoule with other pharmaceutical forms of diclofenac (tablets or suppositories) up to a maximum daily dose of 150 mg. Durilac in the form of ampoules should not be used more than two days; if it is necessary, the treatment can continue with diclofenac tablets or suppositories. Durilac, solution for injection is not recommended to be used in children.
Intravenous dose: Diclofenac is given as a continuous intravenous infusion or intermittent, diluted with glucose 5% or sodium chloride 0.9% (buffered previously with sodium bicarbonate 8.4%).
For the treatment of postoperative pain, a dose of 75 mg may be given over 30 to 120 minutes. The dose can be repeated if necessary after 4 or 6 hours.
To prevent postoperative pain, it is used as an initial dose of 25 to 50 mg over 15 to 60 minutes after surgery followed by 5 mg/hour to a maximal dose of 150 mg / day. The maximum period recommended for parenteral use of diclofenac ampoules is 2 days.

As a rule, Durilac should be used with particular caution in elderly patients as well as the recommended maximum daily dose should be reduced in patients with low body weight (less than 60 kg).

If you have taken more Durilac than you should
If you take more Durilac than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you have forgotten to take Durilac
If you forget a dose (or more doses), take the following dose when it is time to take it usually. Do not take a double dose (or higher) to make up for the forgotten dose (doses).
If you have further questions on the use of this product, ask your doctor or pharmacist.
The above advices are valid in the case of Durilac – suppositories and solution for injection.

4. POSSIBLE SIDE EFFECTS
Like all other medicines, Durilac can cause side effects, although not everybody manifests them. Sometimes they are serious, sometimes not. Do not get alarmed by this list of the possible side effects. You may get none of them.
Some patients may complain of epigastric pain, nausea and diarrhea. These symptoms can be alleviated or disappear with the continuation of the medication. Other effects are: dry mouth, fatigue, visual disturbances, convulsions, which are very rarely observed.
There may appear skin reactions such as: erythema multiforme, Stevens - Johnson syndrome, Lyell's syndrome, hair loss, photosensitivity, itching, redness or rash.
When the gel is used for a long period of time and in a large skin surface, can not be ruled out completely the possibility of the occurrence of adverse systemic effects; in such cases, you should consult your doctor immediately.
If any of the side effects worsens, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DURILAC
Keep this medicine out of the sight and reach of children.
Do not use Durilac after the expiry date which is stated on the carton box.
Do not store in a temperature above 25°C.
Keep in the original packaging to protect it from light.

6. OTHER INFORMATION
What Durilac – suppositories 100 mg contain:
The active substance is diclofenac sodium.
1 suppository contains 100 mg diclofenac sodium.
Other excipients: colloidal anhydrous silica and hard fat.

What Durilac – gel 1 % contains:
The active substance is diclofenac sodium.
1 g of gel contains 10 mg of diclofenac sodium.
Other excipients: ethanol 96 %, menthol, benzyl alcohol, Labrasol, hydroxypropyl cellulose, purified water.

What Durilac – solution for injection 75 mg / 3 ml contains:
The active substance is diclofenac sodium.
1 ampoule with 3 ml of solution for injection contains 75 mg diclofenac sodium.
Other excipients: mannitol, benzyl alcohol for injection, propylene glycol, sodium metabisulphite, anhydrous sodium sulphite, water for injection.

Contents of the pack:
Durilac – suppositories 100 mg:
Carton box with 10 suppositories.

Durilac – gel 1 %:
Carton box with 1 tube of 30 g.

Durilac – solution for injection 75 mg / 3 ml:
Carton box with 10 ampoules 3 ml.
Carton box with 100 ampoules 3 ml (for hospital use).

Explanation of illustrated icons in the packing:

Content. Warning!

Suppositories. Ampoules. Gel.

According to medical prescription! Without medical prescription!

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.Fax: 00355 4 23 62 800
Tirana - Albania

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SPECIFICATION

CROPING AREA 15 x 25 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.