

Package leaflet: Information for the patient
DAGAMOL
(Diclofenac Sodium & Paracetamol Tablets)

Please read this leaflet carefully before using this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

In this leaflet:

- 1. What DAGAMOL Tablets is and what it is used for?**
- 2. Before you take DAGAMOL Tablets**
- 3. How to take DAGAMOL Tablets?**
- 4. Possible side effects**
- 5. How to store DAGAMOL Tablets?**
- 6. Further information**

1. What DAGAMOL Tablets is and what it is used for?

DAGAMOL (Diclofenac Sodium & Paracetamol 50mg/500mg) Tablet is a pain relieving medicine. It is used to reduce pain and inflammation in conditions like rheumatoid arthritis, ankylosing spondylitis, and osteoarthritis. It may also be used to relieve muscle pain, back pain, toothache, fever, or pain in the ear and throat.

DAGAMOL Tablet should be taken with food. This will prevent you from getting an upset stomach. You should take it regularly as advised by your doctor. Do not take more or use it for a longer duration than recommended by your doctor.

2. Before you take DAGAMOL Tablets

Do not take **DAGAMOL** tablets if you are allergic to Diclofenac Sodium & Paracetamol or any other NSAID or to any of the ingredients listed in section 6 of this leaflet.

If you think you may be allergic to diclofenac potassium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of **DAGAMOL** Tablets. (These are listed at the end of the leaflet.) 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.

- You have now, or have ever had, a stomach (gastric) or duodenal (peptic) 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)

- you have had stomach or bowel problems after you have taken other NSAIDs
- you have heart, kidney or liver failure
- if you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- you are more than six months pregnant.

You should also ask yourself these questions before taking DAGAMOL Tablets:

- Do you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease?
- Do you have kidney or liver problems, or are you elderly?
- Do you have a condition called porphyria?
- Do 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.
- Have you ever had asthma?
- Are you breast-feeding?
- Do you have angina, blood clots, high blood pressure, abnormally high levels of fat in your blood (raised cholesterol or raised triglycerides)?
- Do you have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, or high cholesterol or are a smoker)?
- Do you have diabetes?
- Do you smoke?
- Do you have Lupus (SLE) or any similar condition?

Pregnancy

- Are you pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take DAGAMOL Tablets during the last 3 months of pregnancy as it may affect the baby's circulation.
- Are you trying for a baby? Taking DAGAMOL Tablets may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

3. How to take DAGAMOL Tablets?

The doctor will tell you how many DAGAMOL Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor. Take the tablets with or after food. DAGAMOL Tablets are specially formulated to act quickly. Swallow the tablets whole with a drink of water. Do not crush or chew them.

The usual doses are:

Adults 75 mg to 150 mg daily divided into two or three doses. The number of tablets you take will depend on the strength the doctor has given you.

For the relief of migraine in adults: Take 50 mg at the first signs of an attack. If the migraine has not gone after 2 hours, take another 50 mg. You can take further doses at intervals of 4 to 6 hours if necessary, but you must not take more than 200 mg in a day.

Elderly

Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the DAGAMOL Tablets are not affecting your stomach.

Children over 14

75 mg to 100 mg daily divided into two or three doses.

DAGAMOL Tablets are not recommended for children under 14. They are not recommended for the treatment of migraine in children of any age. The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

What if you forget to take a dose?

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed. Do not double up on the next dose to make up for the one missed. Do not take more than 150 mg (three 50 mg tablets or six 25 mg tablets) in 24 hours.

What if you take too many tablets?

If you, or anyone else, accidentally takes too much, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

4. Possible side effects

DAGAMOL Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary. Some side effects can be serious. Stop taking DAGAMOL Tablets and tell your doctor straight away if you notice:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- 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.
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm)
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with DAGAMOL Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome. If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

5. How to store DAGAMOL Tablets?

Store in a dry place, below 30°C. Keep the tablets in their original pack.

Keep out of the reach and sight of children.

Do not take **DAGAMOL** Tablets after the expiry date which is printed on the outside of the pack. If your doctor tells you to stop taking the tablets, please take any unused tablets back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Further information

DAGAMOL Tablet contains:

Active substance:

Each uncoated tablet contains: Diclofenac Sodium 50 mg & Paracetamol 500 mg.

Other ingredients: Maize Starch, Dicalcium Phosphate, Sodium Benzoate, Aerosil, P.V.P.K.-30, Magnesium Stearate, Talcum, Sodium Starch Glycolate.

What DAGAMOL Tablet looks like and contents of the pack:

White coloured, Round Shaped, Flat beveled edged uncoated bisected line on one side.

Supplier and Manufacturer

Centurion Remedies Pvt. Ltd.

Plot No: G-5/6, B.I.D.C. Gorwa

Baroda-390016, India.

Tel: 91-265-2282061, 3290522, 2281074

Fax: 91-265-2280436

E-mail: cen_lab@rediffmail.com

Local Representative's Name & Address

Blister's Ltd.,

Post Office 89, Ashaiman,

Tema, Ghana.

Date of publication or revision

07/2016