

Package leaflet: Information for the user

MOLFEN TABLETS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Molfen tablets are and what they are used for
2. What you need to know before you take Molfen Tablets
3. How to take Molfen Tablets
4. Possible side effects
5. How to store Molfen Tablets
6. Contents of the pack and other information

1. What Molfen Tablets tablets are and what they are used for Molfen Tablets contain:

Paracetamol and ibuprofen. Paracetamol works to stop the pain messages from getting through to the brain. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs).

It relieves pain and reduces inflammation (swelling, redness or soreness). Molfen Tablets tablets are used for short-term symptomatic treatment of mild to moderate pain.

Ask your doctor or pharmacist if you have any questions about this medicine. You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Molfen Tablets Do not take Molfen Tablets :

if you are allergic to the active substance(s) or any of the other ingredients of this medicine

if you have a history with gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; -
you have an active or recurrent peptic ulcer (i.e. stomach or duodenal ulcer), or bleeding (two or more distinct episodes of proven ulceration or bleeding); -

if you regularly drink large quantities of alcohol – ,If you have severe heart failure, hepatic failure or renal failure –

if you have cerebrovascular or other active bleeding – ,if you have blood-formation disturbances –

if you have asthma, urticaria or allergic-type reactions after taking acetylsalicylic acid or other NSAIDs - during the last three months of pregnancy –

if you are under the age of 18 years Warnings and precautions Talk to your doctor or pharmacist before taking Molfen Tablets.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses.

Do not exceed the recommended dose or duration of treatment. Page 2 of 6 You should discuss your treatment with your doctor or pharmacist before taking Molfen Tablets.

if you: • have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”).

- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Tell your doctor or pharmacist if: • you have liver disease, hepatitis, kidney disease or difficulty urinating;

- you are a drug user; • you are pregnant or intend to become pregnant;
- you are breast-feeding or plan to breast-feed; • you currently have an infection; • you plan to have surgery;
- check that other medicines do not contain paracetamol,
- observe the maximum recommended doses .

Do not drink alcoholic beverages when taking this medication. Combining alcohol with Molfen Tablets may lead to liver damage.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine. The prolonged use of analgesics can result in headache which must not be treated by increasing the dose of the medicine.

Taking this medicine may interfere with the results from the urine analysis test for 5-hydroxyindoleacetic acid (5HIAA), causing false-positive results. To avoid false results do not take this medicine or other paracetamol containing products for several hours before or during the collection of the urine specimen.

Children and adolescents This product is contraindicated in children under 18 years. Other medicines and Molfen Tablets.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Molfen Tablets may affect or be affected by some other medicines.

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines to treat epilepsy or fits, • chloramphenicol, an antibiotic used to treat ear and eye infections
- probenecid, a medicine used to treat gout, • zidovudine, a medicine used to treat HIV (the virus that causes acquired immunodeficiency disease)
- medicines used to treat tuberculosis such as isoniazid,• salicylates or other NSAID medicines
- diuretics, also called fluid tablets ,• lithium, a medicine used to treat some types of depression
- methotrexate, a medicine used to treat arthritis and some types of cancer,• corticosteroids, such as prednisone, cortisone
- metoclopramide, propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- cholestyramine, a medicine used to reduce raised serum lipid levels
- tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant ,• sulphonylureas, a medicine used to treat diabetes
- some antibiotics (such as quinolone antibiotics or co-trimoxazole)
- cardiac glycosides, medicines to strengthen the heart. Some other medicines may also affect or be affected by the treatment of Molfen tablets.

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine. Pregnancy, breast-feeding and fertility If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine during the last 3 months of your pregnancy. Take special care when taking this medicine if you are in the first 6 months of pregnancy. You should use the lowest possible dose that reduces your pain and use it for the shortest time possible. Contact your doctor or midwife if the pain is not reduced or if you need to take the medicine more often.

This product may impair female fertility and is not recommended in women attempting to conceive. Driving and using machines Be careful driving or operating machines until you know how Molfen Tablets affect you. contact your doctor before taking this medicinal product.

3. How to take Molfen Tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is: Adults: 1 Caplet 3-4 times daily aftermeals or As directed by the physician. You should consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

CONTAINS PARACETAMOL. Do not take any other paracetamol-containing products. Do not exceed the stated dose. Immediate medical advice should be sought in the event of overdosage, because of the risk of irreversible liver damage. Use in children under 18 years Molfen Tablets are contraindicated in children under 18 years. If you take more Molfen Tablets than you should Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you have taken more Molfen Tablets than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken. The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported. If you forget to take Molfen Tablets. If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for a forgotten dose. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. If any of these serious side effects happen, stop taking Molfen Tablets and tell your doctor immediately or go to the emergency room at your nearest hospital:

- In patients with known hypersensitivity to Ibuprofen, Paracetamol or any other excipients.
- In patients with a history of hypersensitivity reactions (e.g. Bronchospasm, angioedema, asthma, angioedema, asthma, rhinitis or urticaria) associated with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).

- Patients with defects in coagulation.
- In patients with severe hepatic failure, severe renal failure or severe heart failure.

5. How to store Molfen Tablets

Keep this medicine out of the sight and reach of children. Store in a cool place and dry place not above 30°C.

Store in the original blister package in order to protect from light. Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXPIRY. The expiry date refers to the last day of that month. Do not use this medicine if you notice packaging is torn or shows signs of tampering. Do not throw away any medicines via wastewater or household waste.

6. FURTHER INFORMATION

Contents of the pack and other information

Molfen Caplets Skillet contains 10 blister strips of 10 Uncoated caplets each with a packing insert.

What Molfen Tablet contains:

Each uncoated Tablets Contains:

Paracetamol BP 325mg

Ibuprofen BP 400mg

A white biconvex capsule-shaped uncoated caplet with M/G on one side.

Manufactured by:

M&G PHARMACEUTICALS LTD.

D, 446/1 Bannerman Road,

James Town, Accra, Ghana.

Email: mgpharm@vodafone.com.gh

TEL: 0302 666613

FAX: 0302 669085

This leaflet was last approved on: 20, Mar 2020