1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

Name of the medicinal product
FLEXDOL tablets
Methocarbamol 500 mg/ibuprofen 200 mg

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

In this package leaflet:

1. WHAT FLEXDOL IS AND WHAT IT IS USED FOR ?
2. BEFORE YOU TAKE FLEXDOL
3. HOW TO TAKE FLEXDOL ?
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE FLEXDOL ?
6. FURTHER INFORMATION

1. WHAT FLEXDOL IS AND WHAT IT IS USED FOR?
This medicine reduces the pain associated with muscles contractions, such as backache, tensions in the muscles of the neck, pulled muscles and sprains.

2. BEFORE YOU TAKE FLEXDOL
Do not take FLEXDOL in the following cases:
- history of allergy to methocarbamol,
- history of allergy or asthma triggered by taking ibuprofen or a related medicine, particularly other non-steroidal anti-inflammatory drugs (NSAIDs), acetylsalicylic acid,
- history of allergy to other constituents of the tablet,
- active stomach or duodenal ulcer,
- serious liver disease,
- serious kidney disease,
- serious heart disease,
- systemic lupus erythematosus,
- myasthenia (serious muscle disease),
- history of convulsive attacks,
- after 5 complete months of pregnancy (24 weeks of amenorrhea);

This medicine MUST GENERALLY NOT BE USED, unless otherwise instructed by your doctor, during pregnancy and breastfeeding.
IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST
Be careful with FLEXDOL:
Consuming alcoholic drinks whilst taking the treatment is strictly not recommended.
Use this medicine *WITH CARE* if you have renal insufficiency: inform your doctor who may decide to change your dose.

At high doses, in excess of 1200 mg/day, ibuprofen possesses anti-inflammatory properties and can occasionally cause serious risks as observed with anti-inflammatory drugs.

BEFORE TAKING THIS MEDICINE, INFORM YOUR DOCTOR, IF YOU:
- have a history of asthma associated with chronic rhinitis, chronic sinusitis or nasal polyps. The administration of ibuprofen can lead to an asthma attack, particularly in some subjects allergic to acetylsalicylic acid or NSAIDs.
- are taking an anticoagulant treatment. This medicine can lead to serious gastro-intestinal events.
- have a history of digestive problems (hiatus hernia, haemorrhage of the digestive tract, previous ulcer of the stomach or of the duodenum).
- have heart, liver or kidney disease.
- have chickenpox.

DURING THE TREATMENT, IF YOU DEVELOP:
- a vision disorder, INFORM YOUR DOCTOR,
- a gastro-intestinal haemorrhage (blood in the mouth, presence of blood in the faeces or black coloration of the faeces), STOP THE TREATMENT AND CONTACT A DOCTOR OR AN EMERGENCY MEDICAL SERVICE IMMEDIATELY.
- burn like signs on your skin or mucous membranes (redness with blisters, ulceration), STOP THE TREATMENT AND CONTACT A DOCTOR OR AN EMERGENCY MEDICAL SERVICE IMMEDIATELY.
- signs suggesting allergy to this medicine, particularly an asthma attack or sudden swelling of the face and neck (see section Possible side effects), STOP THE TREATMENT AND CONTACT A DOCTOR OR AN EMERGENCY MEDICAL SERVICE IMMEDIATELY.

This medicine contains a non-steroidal anti-inflammatory drug: **ibuprofen**.
You must not take this medicine at the same time as other medicines containing non-steroidal anti-inflammatory drugs (NSAIDs) and/or acetylsalicylic acid.
Read carefully the package leaflets of the other medicines that you take to make sure they do not contain NSAIDs and/or acetylsalicylic acid.

IF YOU HAVE ANY DOUBT DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking other medicines
In order to prevent any drug interactions, particularly with oral anticoagulants, other NSAIDs including acetylsalicylic acid and its derivatives, heparin, lithium, methotrexate (more than 15 mg a week), you must systematically report any other treatment you are currently taking or have taken recently to your doctor or pharmacist.
Pregnancy and Breastfeeding:
The use of this medicine is not recommended during pregnancy and breastfeeding.
If you discover that you are pregnant during the treatment, see your doctor as soon as possible, only he/she will be able to adapt the treatment to your condition.
IN GENERAL, ALWAYS ASK YOUR DOCTOR OR PHARMACIST BEFORE TAKING A MEDICINE DURING PREGNANCY OR WHILE BREASTFEEDING.
Driving vehicles and use of machines
The attention of patients who drive vehicles and use machines is drawn to the risk of drowsiness and dizziness.

3. HOW TO TAKE FLEXDOL ?
Dosage:
The medicine is only for adults (aged over 15 years)

Take the tablets with a glass of water, preferably at the start of meals.
1 or 2 tablets every 4 to 6 hours. Do not exceed 6 tablets per 24 hours, unless otherwise prescribed by your doctor.
Method and route of administration
Oral route.
Take the tablets preferably at the start of meals.

If you have taken more FLEXDOL tablets than you should:
An overdose of methocarbamol may cause excessive drowsiness, blurred vision, hypotension, convulsions and coma.
In the event of overdose or accidental intoxication, inform your doctor immediately.

4. POSSIBLE SIDE EFFECTS
Like all medicines, FLEXDOL tablets may cause side effects, although not everybody gets them:

Effects associated with methocarbamol: risk of drowsiness, rarely skin reactions, fever, nausea, dizzy spells, headaches, loss of appetite, superficial inflammation of the eye, vision disorders.
Methocarbamol can cause a brown or green coloration of the urine, which is not harmful.

Effects associated with ibuprofen:
- allergic reactions may occur:
  - skin: eruption on the skin, itch, oedema, urticaria, aggravation of chronic urticaria,
  - respiratory system: asthma attack,
  - generalised: sudden swelling of the face and neck (Quincke's oedema).
- in some rare cases, a gastro-intestinal haemorrhage may occur. These are more frequent at higher doses.
- exceptionally, headaches accompanied by nausea, vomiting and stiffness of the neck have been observed.
- exceptionally, serious skin infections have been observed in the event of chickenpox.
- Very exceptionally blistering symptoms of the skin or mucous membranes can occur (burning sensation accompanied by redness with blisters, formation of ulcers).

In all these cases, <u>you must stop the treatment immediately and alert your doctor</u>.
- during the treatment, it is possible that the following may occur:
  - digestive tract disorders: stomach ache, vomiting, nausea, diarrhoea, constipation,
  - exceptionally: dizzy spells or headaches, rare disorders of the vision, significant reduction in the urines output, renal insufficiency, changes in the hepatic picture or the composition of the blood (reduction in the white or red cells) that may be serious.

In all these cases, <u>you must alert your doctor</u>.
If you notice any side effects not mentioned in this package leaflet, or if some side effects become serious, please tell your doctor or pharmacist.

5. HOW TO STORE FLEXDOL ?
Keep out of the reach and sight of children.
Do not use FLEXDOL after the expiry date stated on the outer pack.
Store at a temperature not exceeding 30°C.
Medicines must not be disposed of down the drain or with the domestic waste. Ask your pharmacist what you should do with unused medicines. These measures are to protect the environment.

6. FURTHER INFORMATION
What does FLEXDOL contain?
The active substances are methocarbamol (500 mg) and ibuprofen (200 mg)

The other ingredients are: microcrystalline cellulose, sodium starch glycolate, maize starch, povidone K-30, talc, magnesium stearate.

What FLEXDOL looks like and contents of the pack?

This medicine is presented in the form of white, elongated, scored tablets. Boxes of 10 tablets in blister pack.

FLEXDOL® is a registered trademark
of Exphar s.a.
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Manufacturer:
Gracure Pharmaceuticals Ltd.,
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