

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zomorph capsules

(morphine sulfate, 10mg, 30mg, 60mg, 100mg, 200mg)

Read all of this leaflet carefully before you start taking this medicine.

- Please 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 you suffer from any side effects that get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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1. What Zomorph capsules are and what they are used for
2. Before you take Zomorph capsules
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1. WHAT ZOMORPH CAPSULES ARE AND WHAT THEY ARE USED FOR

Zomorph capsules belong to a group of medicines called opioid analgesics. They contain the active ingredient morphine sulfate in a special slow-release form which gives relief from severe pain, particularly pain associated with cancer.

2. BEFORE YOU TAKE ZOMORPH CAPSULES

DO NOT take Zomorph capsules if:

- you have an allergy (hypersensitivity) to morphine sulfate or any of the other ingredients in the product (*see Section 6 and end of Section 2*)
- you have breathing difficulties
- you have unexplained abdominal pains
- you have liver problems
- you have raised intracranial pressure (severe headache), for example from a head injury
- you have convulsions (fits)
- you have recently consumed a large amount of alcohol, or have been intoxicated
- paralytic ileus (bowel obstruction)
- you have ever taken monoamine oxidase inhibitors (MAOIs) for depression, or have done so in the last 14 days
- the patient is a child.

Take special care with Zomorph capsules

The dose should be reduced or stopped if you:

- are elderly
- are in a state of shock
- have liver or kidney problems
- have an underactive thyroid or adrenal gland
- have asthma.

The capsules should be used with caution if you have:

- low blood pressure
- convulsions (fits)
- dependence (severe withdrawal symptoms if the medicine is withdrawn suddenly)
- an enlarged prostate gland, in which case you may have problems passing urine.

If you are going to have **surgery**, tell your doctor or dentist that you are taking Zomorph capsules.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. These include:

- other opioid analgesics, such as buprenorphine, butorphanol, nalbuphine or pentazocine
- medicines for depression, i.e. MAOIs and tricyclic antidepressants
- anaesthetics
- antipsychotics (for psychiatric diseases), anxiolytics (for anxiety), phenothiazines (for schizophrenia)
- hypnotics/sedatives (for sleeping problems)
- cyclizine, mexiletine, metoclopramide, domperidone (for nausea and vomiting)
- ritonavir (for AIDS treatment).

Taking with food and drink

Drinking alcohol whilst taking Zomorph capsules may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you're taking Zomorph capsules.

Pregnancy and breast-feeding

Zomorph capsules should not be taken if you are pregnant, planning to become pregnant or breast-feeding. Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Important information about some of the ingredients of Zomorph capsules

Sucrose - if you know you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sunset yellow (60mg capsules only) - may cause allergic reactions.

3. HOW TO TAKE ZOMORPH CAPSULES

Always take Zomorph capsules exactly as your doctor has told you; check with him/her if you are not sure.

The **usual dose** is:

Adults - one capsule, swallowed whole with a glass of water, every 12 hours.

Elderly - a reduced dose may be prescribed.

If you have difficulty swallowing capsules - The entire capsule contents can be sprinkled onto a spoonful of semi-solid food (such as plain yoghurt) and swallowed.

To open the capsule, hold upright to contain the granules at the bottom then gently squeeze the top and twist to remove, taking care not to spill the contents. **Do not chew or crush the granules.**

If you take more Zomorph capsules than you should

Contact your doctor or nearest casualty immediately if you, or someone you know, have taken too many capsules. Remember to take any remaining medicine and this leaflet with you if possible. Symptoms of overdose include breathing difficulties, extreme miosis (constriction of pupils in the eyes), low blood pressure, a fall in body temperature and coma.

If you forget to take Zomorph capsules

If you remember within 4 hours of missing your dose, take a capsule straight away. Take your next dose at the normal time. If you are more than 4 hours late taking your dose, please call your doctor for advice. Do not take a double dose to make up for the one forgotten.

If you stop taking Zomorph capsules

It is important not to stop taking this medicine until your doctor tells you to. If you have been taking the capsules over a long period of time you may experience withdrawal effects when you stop taking them. Should this occur, please consult your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zomorph capsules can cause side effects, although not everybody gets them.

Skin rashes and itching suggest an **allergic reaction**, in which case you should **stop taking** the tablets immediately and seek urgent medical assistance.

The **most common** side effects are nausea, constipation, confusion and occasionally vomiting. You may also experience the following:

- breathing difficulties
- headache, increased pressure in the brain
- abnormal heart rhythms
- low blood pressure or body temperature
- burning sensation or difficulty when passing urine
- dry mouth, sweating, facial flushing
- drowsiness, dizziness, sedation
- miosis (contraction of the pupil in the eye)
- mood changes, excitation (particularly in the elderly)
- decreased sex drive
- light-headedness when standing
- abdominal pain
- dependence and withdrawal syndrome

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOMORPH CAPSULES

Keep out of the sight and reach of children.

Store below 25°C in a dry place, protected from heat. Do not use Zomorph capsules after the expiry date shown on the pack.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Zomorph capsules contain

The **active** ingredient is morphine sulfate BP; each capsule contains either 10mg, 30mg, 60mg, 100mg or 200mg of this substance.

The **other** ingredients are sucrose, maize starch, polyethylene glycol 4000, ethylcellulose, cetyl alcohol, sodium lauryl sulfate, dibutyl sebacate, talc, gelatin, iron oxide ink (E172), and the following colourings:

- titanium dioxide (E171) - 10mg, 30mg, 60mg and 100mg capsules
- quinoline yellow (E104) - 10mg capsules
- erythrosine (E127) - 30mg capsules
- sunset yellow (E110) - 60mg capsules.

See end of Section 2 for further, important information on sunset yellow and sucrose.

What Zomorph capsules look like & contents of the pack

The capsules are made in different colours to identify each strength:

10mg - yellow/clear 100mg - white/clear
30mg - pink/clear 200mg - clear
60mg - orange/clear

They are packed in aluminium/PVC blisters; each pack contains 6 blisters x 10 capsules.

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