This medicine contains morphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet:
1. What Zomorph capsules are and what they are for
2. What you need to know before you take Zomorph capsules
3. How to take Zomorph capsules
4. Possible side effects
5. How to store Zomorph capsules
6. Contents of the pack and other information

1. WHAT ZOMORPH CAPSULES ARE AND WHAT THEY ARE USED FOR

This medicine has been prescribed for you for relief from severe pain, particularly pain associated with cancer, over a period of 12 hours thanks to its special slow release form.

It contains a morphine which belongs to a class of medicines called opioids, which are ‘pain relievers’. This medicine has been prescribed to its special slow release form.

This medicine has been prescribed for you for relief from severe pain, particularly pain associated with cancer, over a period of 12 hours thanks to its special slow release form.

This medicine contains morphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Of this leaflet: before you take Zomorph capsules

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOMORPH CAPSULES

DO NOT take Zomorph capsules if:

- you are allergic to morphine or any of the other ingredients of this medicine (listed in section 6)
- you have breathing difficulties such as obstructive airways disease or respiratory depression. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected.
- you have unexplained swelling of the legs
- you have a condition where your stomach empties more slowly than it should (delayed gastric emptying)
- you have a severe head injury
- you have recently consumed a large amount of alcohol, or have been intoxicated
- you have a risk of bowel obstruction (paralytic ileus)
- you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.

Talk to your prescriber before taking this medicine if you:

- have an underactive thyroid.
- have liver or kidney problems
- have an undetectable thyroid.

The capsules should be used with caution if you have:

- renal, liver, or heart disease
- if you have a condition where your stomach empties more slowly than it should (delayed gastric emptying)
- if you have a head injury, or if you feel sick. This is because the capsules may make these symptoms worse or hide the extent of the head injury
- you have fits (convulsions)
- you have recently consumed a large amount of alcohol, or have been intoxicated
- you have a risk of bowel obstruction (paralytic ileus)
- you are taking a type of medicine for depression known as monoamine oxidase inhibitors (MAOIs), or have taken this type of medicine in the last 14 days
- the patient is a child

Warning and precautions

Talk to your prescriber before taking this medicine if you:

- are elderly
- have liver or kidney problems

Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or affect your co-ordination. It may make you less able to use machines safely.

Pregnancy, breast-feeding and fertility

Do not take Zomorph capsules if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Zomorph capsules during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Zomorph capsules while you are breastfeeding as morphine passes into breast milk and will affect your baby.

Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or affect your co-ordination. It may make you less able to use machines safely.

- if you have any pain in your legs or feet while you are taking this medicine.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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3. HOW TO TAKE ZOMORPH CAPSULES

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

Your prescriber should have discussed with you, how long the course of treatment will last. They will arrange a plan for stopping treatment. This will outline how gradually to reduce the dose and stop taking the medicine.

The usual dose is:
- Adults - one capsule, swallowed whole with a glass of water, every 12 hours.
- Elderly
- Children and adolescents - usually half a capsule, swallowed whole, every 12 hours.

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 capsules. This can be dangerous, causing serious problems such as an overdose, which may be fatal.

There is a risk that you may become addicted to or dependent on these capsules (a need to keep taking the medicines). If you take these for a long time you can become used to the effects and you may need to take higher doses to control your pain.

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.

People who have taken an overdose may have convulsions, increase in muscle tension, involuntary contractions of the muscles, or a feeling of extreme happiness, hallucinations.

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.

Common (may affect up to 1 in 10 patients):
- Dizziness
- Palpitations
- Tachycardia (fast heart rate)
- Hypertension (high blood pressure)
- Breathing difficulties (possibly due to fluid on the lungs) or wheezing
- Indigestion, blockage of the intestine (ileus)
- Headache
- Abdominal pain
- Swelling of the hands, ankles or feet
- Blood in the stool (blood test results (increased levels of liver enzymes)

Not known (frequency cannot be estimated from available data):
- Decreased sex drive
- Excitation (particularly in the elderly), drug dependence, abnormal thoughts
- Sedation, increased pressure in the brain, pain due to a something which does not normally provoke pain), an increased sensitivity to pain, burning sensation or difficulty when passing urine
- Amenorrhoea (loss of menstruation, impotence
- Local anaesthetic
- Dependence and addiction (see section “How do I know if I am addicted?”)

Abstinence symptoms in babies born to mothers who have used Zomorph (see section “Pregnancy, breastfeeding and fertility”)

Drug Withdrawal
When you stop taking Zomorph capsules, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, an increased sensitivity to pain, abnormal thoughts, anxiety, feeling your heart is racing (palpitations), increased blood pressure, dreaming, feeling or being sick, diarrhea, shaking, or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking Zomorph capsules, it could be a sign that you have become addicted.

You need to take the medicine for longer than advised by your prescriber.

You need to use more than the recommended dose.

You are using the medicine for reasons other than prescribed.

When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber.

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 or search for MIHA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOMORPH CAPSULES

Keep this medicine 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. Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. 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 or 100mg of this substance.

The other ingredients are sucrose, maize starch, polyethylene glycol 4000, ethyl-cellulose, cetyl alcohol, sodium lauryl sulphate, dibutyryl sebacate, talc, titanium dioxide (E172), the following colours:
- titanium dioxide (E171) - 10mg, 30mg, 60mg and 100mg capsules
- quinoline yellow (E104) - 10mg capsules
- sunset yellow (E110) - 60mg and 100mg capsules

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

What Zomorph capsules look like & contents of the pack
The capsules are made in different colours to identify each strength: 10mg - yellow/orange, 30mg - pink/orange, 60mg - green/orange, 100mg - blue/orange.

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

Marketing Authorisation Holder

Manufacturer

Ethypharm

Ethypharm

194, Bureaux de la Colline - Bâtiment D
France

78 120 Grand-Quevilly,

10 60 Grand-Quevilly,

France

France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: United Kingdom: Ethypharm UK - email: medinfo@ethypharm.com

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