

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

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 have any further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What **Zomorph capsules** are and what they are used for
- What you need to know before you take **Zomorph capsules**
- How to take **Zomorph capsules**
- Possible side effects
- How to store **Zomorph capsules**
- 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 morphine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed/provided to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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 problems such as obstructive airways disease, respiratory depression, or severe asthma. 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 severe headache (raised intracranial pressure), for example from 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 a condition where the small bowel (part of your gut) does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen;
- you have recent onset liver disease;
- you are taking a type of medicine for depression known as monoamine oxidase inhibitors (examples include tranlycypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
- the patient is a child under six years of age.

If you are going to have an operation, please tell the doctor at the hospital that you are taking these capsules.

Warning and precautions

Tolerance, dependence, and addiction

This medicine contains morphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of **Zomorph capsules** can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to **Zomorph capsules** if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking **Zomorph capsules**, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ("withdrawal effects")

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking **Zomorph capsules**).

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for.

Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Talk to your doctor or pharmacist before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs;
- feel you need to take more of **Zomorph capsules** to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor who will discuss your treatment and may change your dose or switch

- you to an alternative pain reliever;
- have breathing problems, such as impaired lung function or severe bronchial asthma. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness and coughing;
- have an under-active thyroid gland (hypothyroidism), severe kidney or liver problems as you may need a lower dose;
- have a severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- suffer from, or have ever suffered from epilepsy, seizures, fits or convulsions;
- have low blood pressure;
- have a severe heart problem after long-term lung disease (severe cor pulmonale);
- have inflammation of the pancreas (which causes severe pain in the abdomen and back) or problems with your gall bladder;
- have an inflammatory bowel disorder;
- you suffer from constipation;
- have prostate problems;
- experience weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenal glands producing too little of the hormone 'cortisol', and you may need to take a hormone supplement;
- have loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.

Acute generalized exanthematous pustulosis (AGEP) has been reported in association with **Zomorph capsules** treatment. Symptoms usually occur within the first 10 days of treatment. Tell your doctor if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking **Zomorph capsules** or other opioids. Stop using **Zomorph capsules** and seek medical attention immediately, if you notice any of the following symptoms: blistering, widespread scaly skin or pus-filled spots together with fever.

Sleep-related breathing disorders

Zomorph capsules can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

You may experience hormonal changes while taking these capsules. Your doctor may want to monitor these changes.

All brands of slow-release forms of morphine like **Zomorph capsules** are not equivalent.

Other medicines and Zomorph capsules:

Concomitant use of **Zomorph capsules** and sedative medicines, such as benzodiazepines or related drugs, increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe **Zomorph capsules** together with sedative medicines, the dosage and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor’s dosage recommendation closely.

It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

If you are taking or have recently taken any other medicines, or might take any other medicines, please tell your doctor or pharmacist. If you take these capsules with some other medicines, the effect of the capsules or the other medicine may be changed.

Tell your doctor or pharmacist if you are taking any of the medicines mentioned below.

- Medicines to help you sleep (for example benzodiazepines, tranquilisers, hypnotics or sedatives)
- Medicines to treat psychiatric or mental disorders (such as phenotiazines), anxiolytics (for anxiety)
- Muscle relaxants
- Medicines to treat high blood pressure
- Cimetidine to treat stomach ulcers, indigestion or heartburn
- Certain types of medicines to stop you feeling or being sick
- Medicines used to prevent or relieve the symptoms of an allergy (antihistamines)
- Rifampicin to treat tuberculosis
- Ritonavir to treat HIV
- Medicines to treat Parkinson’s disease
- Gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain)
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine
- Other opioid analgesics, such as buprenorphine, butorphanol, nalbuphine or pentazocine.

Also tell your doctor if you have recently been given an anaesthetic.

Taking Zomorph capsules with alcohol

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 are taking **Zomorph capsules**.

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 doctor 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, such as high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

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

Driving and using machines

These capsules may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the capsules, or when changing to a higher dose. If you are affected, you should not drive or use machinery.

This 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 while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').
- This defence applies when:
 - The medicine has been prescribed to treat a medical or dental problem, and
 - You have taken it according to the instructions given by the doctor and in the information provided with the medicine.

- Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: https://www.gov.uk/drug-driving-law.

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

Zomorph capsules contain sucrose and [60 mg strength only] sunset yellow (E110)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

[60 mg strength only] The capsules contain sunset yellow (E110), which may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using **Zomorph capsules**, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking **Zomorph capsules**, in this section).

Swallow your capsules whole with a glass of water. **Do not break, crush or chew them.**

Zomorph capsules are designed to work properly over 12 hours when swallowed whole. If a capsule is broken, or the content of the capsule is crushed or chewed, the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.

You must only take the capsules by mouth. The content of the capsule should never be crushed or injected as this may lead to serious side effects, which may be fatal.

You should take your capsules every 12 hours. For instance, if you take a capsule at 8 o'clock in the morning, you should take your next capsule at 8 o'clock in the evening.

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

Adults

The usual dose is one capsule, every 12 hours.

However, the dose will depend on your age, weight and the severity of your pain. If you are elderly or weigh less than 70 kg your doctor may suggest a lower dose. Your doctor will decide how many capsules you should take.

Children over six years of age

The required dose will depend on their weight and severity of pain. This should be discussed with your doctor or pharmacist.

If you find that you are still in pain whilst taking these capsules discuss this with your doctor. Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

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 or if someone accidentally swallows your capsules

Call your doctor or nearest hospital immediately if you, or someone you know, have taken too many capsules, as you may need emergency treatment.

People who have taken an overdose may feel very sleepy, sick, dizzy or get pneumonia from inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever).

People who have taken an overdose may also have breathing difficulties leading to unconsciousness or even death.

People who have taken an overdose may also have extreme miosis (constriction of pupils in the eyes), low blood pressure, a fall in body temperature and coma.

When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show to the doctor.

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

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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 every/body gets them.

Stop using **Zomorph capsules** and seek medical attention immediately if you notice any of the following symptoms:

Severe skin reaction with blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).

The most serious side effect, although uncommon, is a condition where you breathe more slowly or weakly than expected (respiratory depression). **Tell your doctor immediately** if this happens to you.

All medicines can cause allergic reactions, although serious allergic reactions are uncommon.

Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

Drug Withdrawal

When you stop taking **Zomorph capsules**, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering 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 doctor
- You feel 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 doctor.

The following side effects may also occur:

Very common side effects (May affect more than 1 in 10 people):

- Constipation (your doctor can prescribe a laxative to overcome this problem)
- Feeling sick (nausea).

Common side effects (may affect up to 1 in 10 people):

- Drowsiness (this is most likely when you first start taking your capsules or when your dose is increased, but it should wear off after a few days).
- Dry mouth, loss of appetite (anorexia), abdominal pain or discomfort
- Vomiting (being sick). This should normally wear off after a few days. However, your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.
- Dizziness, headache, confusion, difficulty in sleeping
- A feeling of unusual weakness
- Generally feeling unwell, tiredness
- Involuntary muscle contractions
- Rash or itchy skin
- Sweating.

Uncommon side effects (may affect up to 1 in 100 people):

- Withdrawal symptoms (see section 'Drug Withdrawal')
- Difficulty in breathing (possibly due to fluid on the lungs) or wheezing
- A condition where the bowel does not work properly (ileus)
- Changes in taste, indigestion
- A feeling of dizziness or 'spinning', fainting, seizures, fits or convulsions
- Agitation, mood changes, hallucinations, a feeling of extreme happiness
- Unusual muscle stiffness
- Tingling or numbness
- Difficulty in passing urine
- Low blood pressure, facial flushing (redness of the face)
- Palpitations
- Swelling of the hands, ankles or feet
- Hives
- A worsening in liver function tests (seen in blood test)
- Blurred vision
- Muscle spasms.

Frequency not known (frequency cannot be estimated from the available data):

- Sleep apnoea syndrome (breathing pauses during sleep)
- Dependence and addiction (see section "How do I know if I am addicted?")
- Unpleasant or uncomfortable mood, abnormal thoughts
- An increased sensitivity to pain
- Reduction in size of the pupils in the eye
- A fast or slow heartbeat
- High blood pressure
- Decreased cough reflex
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system, e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever
- Impotence, decreased sexual drive, absence of menstrual periods
- Withdrawal symptoms in babies born to mothers who have used **Zomorph capsules** in pregnancy (See section 2 'Pregnancy, breastfeeding and fertility').

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 MHRA 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 stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER 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, ethyl-cellulose, 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
30mg - pink/clear
60mg - orange/clear
100mg - white/clear
200mg - clear.

They 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	Chemin de la poudrière,
92213 Saint-Cloud cedex	76 120 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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