

## Front Face Design & Text

### **Kaolin & Morphine Mixture**

**Kaolin, Sodium Hydrogen Carbonate, Morphine Hydrochloride**

**Relieves the symptoms of diarrhoea and upset stomachs**

**Can cause addiction**

**Contains opioid**

**<Information in Braille: Kaolin & Morphine Mixture>**

**IMPORTANT: Peel this label at corner and read BEFORE use. Do not tear off, re-fix for future use.**

For symptomatic relief of diarrhoea and upset stomachs.

**SHAKE THE BOTTLE.** Take the suspension by mouth.

**Adults, the elderly and children over 12 years:**

Take 2 x 5ml spoonfuls. Repeat up to three times a day if required.

**Do not give to children under 12 years old.**

**DO NOT TAKE MORE MEDICINE THAN THE LABEL TELLS YOU TO.**

Do not take with alcoholic or hot drinks.

**Peel where shown for further precautions.**

**Active ingredients per 10ml:** kaolin light 2g, sodium hydrogen carbonate 500mg, morphine hydrochloride 0.916mg.

**Also contains amongst other ingredients:**

ethanol (0.46 vol%), sucrose, parahydroxybenzoates (E219, E217), sodium (148mg/10ml), benzyl alcohol (E1529) (0.05ug/10ml).

**Peel where shown for full list of ingredients.**

Do not store above 25°C. Keep tightly closed.

**Keep out of the sight and reach of children.**

Manufactured by the licence holder L.C.M. Ltd., Huddersfield, HD7 5QH, UK for Thornton and Ross Ltd., Huddersfield, HD7 5QH, UK.

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200ml e

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<LOT, manufacture & expiry date>

## Remaining Text

This medicine contains kaolin to help remove toxic substances from the digestive system and increase the bulk of solid waste. It also contains sodium hydrogen carbonate which neutralizes excess stomach acid and morphine which calms the gut.

### 1. Before you use this medicine



**Do not use the medicine if you or your child have....**

- An **allergy** to any of the ingredients listed in section 3.
- A **blocked intestine or bowel problems.**
- **Liver disease.**
- **Shallow breath, breathing difficulties or during an asthma attack.**
- A **head injury or persistent headache.**
- **Fits or seizures.**
- A **coma.**
- Taken **MAOIs (monoamine oxidase inhibitors)** for depression within the last two weeks.
- An **addiction to alcohol.**
- **High levels of alkali in the blood.**
- **Low levels of calcium in the blood.**
- **Reduced stomach acid.**



**Warnings and precautions**

**Talk to your doctor or pharmacist if you or your child have....**

- Heart failure.
- Kidney problems.
- Liver problems.
- High or low blood pressure.
- Prostate trouble.
- An underactive thyroid.
- Asthma.

- A low sodium diet.
- Or are taking steroids.
- Or you are elderly, or weakened, as these people can react differently to the medicine and may need a lower dose.

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

This medicine 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.

### **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 this medicine 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 this medicine 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 this medicine, 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 or pharmacist
- You need to take more than the recommended dose
- You are using the medicine for reasons other than indicated, 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.



**Talk to your doctor or pharmacist if you or your child are taking....**

- Medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine.
- Any tranquillisers, sleeping tablets, antidepressants or medicines for mental illness (including MAOIs, tricyclics, moclobemide, phenothiazines).
- Antihistamines which cause drowsiness.
- Alcohol.
- Aspirin.
- Antibiotics, e.g. ciprofloxacin, tetracycline.
- Medicines to regulate heartbeat, e.g. esmolol.
- Antivirals, e.g. ritonavir.
- Gabapentin or pregabalin to treat epilepsy and pain due to nerve problems (neuropathic pain).
- Domperidone or metoclopramide - which stop you feeling or being sick.
- Cimetidine for a stomach ulcer.
- Sodium oxybate for serious daytime sleepiness.
- Chloroquine or hydroxychloroquine – to prevent or treat malaria.
- Any other medicine as this medicine may interfere with their action.

Concomitant use of this product 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 this product together with sedative medicines the dose 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 dose 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.

### **Pregnant or breastfeeding....**

Kaolin & Morphine Mixture should not be used in pregnancy or breastfeeding unless the doctor has told you to do so.

### **Driving and using machines....**

This medicine may cause drowsiness. If you are affected do not drive or operate machinery.

### **Important ingredient information**

Each 10ml dose of this medicine contains:

- 0.16g sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- 38mg ethanol, which is equivalent to 0.38% w/v. The amount in 10ml is equivalent to less than 1ml of beer and 1ml of wine. The small amount of alcohol in this medicine will have no noticeable effects.
- 6.4mmol or 148mg sodium (main component of cooking/table salt). This is equivalent to 7.4% of the recommended maximum daily dietary intake of sodium for an adult.
- 0.05µg benzyl alcohol, which may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast feeding, or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build up in your body and may cause side effects (called “metabolic acidosis”).
- 65mg sodium methyl and 6.8mg sodium propyl hydroxybenzoates (E219, E217) which may cause allergic reactions (possibly delayed).
- 70mg fructose.
- 0.175mg benzyl benzoate, which is equivalent to 0.00175% w/v.

## **2. Possible side effects**

Like all medicines, Kaolin & Morphine Mixture can have side effects, although these don't affect everyone.

**Possible side effects are:**

- Stomach cramps
- Wind
- Feeling or being sick
- Constipation
- Drowsiness
- Confusion
- Difficulty in passing water
- Dry mouth
- Sweating
- Headache
- Facial flushing
- Dizziness
- Low body heat
- Hallucinations
- Mood changes
- Pinpoint pupils
- Low sexual urge
- Skin rash and itching
- Low blood pressure
- Abnormal heartbeat
- An increased sensitivity to pain
- Prolonged use may lead to dependence
- Severe skin reaction (blistering, widespread scaly skin, pus-filled spots) together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP)
- Sleep apnoea (breathing pauses during sleep)
- 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.

If you notice these or any other side effects, stop use and tell your doctor or pharmacist. They will tell you what to do.

**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 at [www.mhra.gov.uk/yellowcard](http://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.

### 3. Further information

If you accidentally take too much see a doctor straight away. Take the pack with you to show which medicine you have swallowed.

- Do not use after the expiry date. The expiry date refers to the last day of that month.
- Return any unused medicine to the pharmacy for disposal.

**The active ingredients per 10ml are:** kaolin light 2g, sodium hydrogen carbonate 500mg, morphine hydrochloride 0.916mg.

**The other ingredients are:** ethanol, peppermint oil, anise oil, saccharin sodium, sodium methyl and sodium propyl hydroxybenzoates (E219, E217), black treacle, liquorice flavour, (contains E1518 glyceryl triacetate, E1520 propylene glycol, E1505 triethyl citrate and E1529 benzyl alcohol) sucrose and purified water.

#### **What the medicine looks like**

Kaolin & Morphine Mixture is a pale brown suspension which separates on standing.

It is supplied in 200ml bottles.

**This label was last revised in September 2023**