

## Package Leaflet: Information for the user

### **OPILON® 40 mg Tablets** Moxisylyte hydrochloride

**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**

1. What Opilon is and what it is used for
2. What you need to know before you take Opilon
3. How to take Opilon
4. Possible side effects
5. How to store Opilon
6. Contents of the pack and other information

#### **1. What Opilon is and what it is used for**

Opilon tablets contain the active ingredient moxisylyte hydrochloride (equivalent to 40 mg of moxisylyte).

Opilon is a “vasodilator” which works by widening the blood vessels and improving blood circulation.

Opilon is used for the short-term control of Raynaud’s Phenomenon in adults. This is a condition where the fingers and toes become discoloured and is triggered by responses to cold, or emotional distress. Opilon helps by improving blood circulation to the extremities.

#### **2. What you need to know before you take Opilon**

##### **Do not take Opilon :**

- if you are allergic to moxisylyte or any of the other ingredients of this medicine (listed in section 6)
- if you have liver disease

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Opilon if any of the following applies to you:

- diabetes
- high blood pressure
- taking tricyclic antidepressants
- are over 65 years of age

##### **Children and adolescents**

This medicine is not intended for children under 18 years.

##### **Other medicines and Opilon**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, because Opilon may interact with them:

- **antihypertensives** (to reduce high blood pressure): Opilon may increase their effect.
- **antidiabetic medicines** (to treat diabetes): your insulin requirement may be reduced.
- **tricyclic antidepressants** (to treat panic and anxiety disorders and some types of pain): this may increase the blood pressure lowering effects of Opilon.

If you are not sure which medicines you are already taking, please ask your doctor or pharmacist.

### **Pregnancy and breast-feeding**

Opilon is not recommended for use if you are pregnant, think you might be pregnant or are planning to become pregnant, as its safety has not been established.

Do not breast-feed if you are taking Opilon.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

There are no known effects of taking Opilon on driving or using machines.

### **Opilon contains Lactose and Ponceau Red (E124)**

This product contains lactose – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The film coating of Opilon tablets contains the colouring agent ponceau red (E124) – may cause allergic reactions.

## **3. How to take Opilon**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose varies from person to person and depends on your condition.

Your doctor will tell you how many tablets to take and for how long you should take them.

Swallow the tablets whole with some water.

Try to take the tablets at the same time every day.

If there is no improvement within two weeks of starting Opilon, your doctor will probably stop your treatment.

### **Adults:**

The usual starting dose is one 40 mg tablet four times a day. Your doctor may increase your dose to two tablets four times a day if your initial response is poor. If you are exposed to the cold during the daytime, one tablet should be administered every three hours during the period when symptoms are most likely to occur.

### **Elderly (over 65 years):**

The dosage is the same as stated for adults, but the elderly should take special care when taking Opilon.

### **Use in children and adolescents:**

Opilon is not recommended for use in children under 18 years old.

**If you take more Opilon than you should**

If you accidentally take more tablets than you should, or you suspect that a child has swallowed the tablets, contact your doctor straight away or go to your nearest hospital casualty department immediately. Take this leaflet and the pack of tablets along with you, if you can.

In excessive overdosage, you may experience a drop in blood pressure; you may need to lie down until your blood pressure is back to normal.

**If you forget to take Opilon**

If you forget to take your tablets, take your next dose as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose. If in doubt about what you should do, please contact your doctor or pharmacist.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Opilon** and seek immediate medical attention if you experience the following:

- jaundice (yellowing of the skin and eyes). This side effect is rare and may indicate that the medicine has affected your liver.

Other side effects that have been reported are:

- mild nausea (feeling sick)
- diarrhoea
- headache
- flushing of the face
- giddiness (a feeling of dizziness or spinning)
- rash

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://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 Opilon**

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP:' and on blister 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 protect the environment.

## **6. Contents of the pack and other information**

### **What Opilon contains**

The active substance is moxislyte hydrochloride, each tablet contains 45.22 mg (equivalent to moxislyte 40 mg).

The other ingredients in the tablet core are lactose, maize starch, microcrystalline cellulose, magnesium stearate and silicon dioxide.

The tablet coating contains hypromellose (E464), propylene glycol, titanium dioxide (E171), quinoline yellow (E104), ponceau 4R (E124) and indigo carmine (E132).

(please see end of section 2 “Opilon contains” for further information on some of the ingredients).

### **What Opilon looks like and contents of the pack**

Opilon tablets are small, round, unmarked, pale yellow film-coated tablets.

The tablets are supplied in blister packs containing 112 tablets.

### **Marketing Authorisation Holder**

Kyowa Kirin Limited  
Galabank Business Park  
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### **Manufacturer**

Recipharm Limited  
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