

Solpadeine[®]

MIGRAINE IBUPROFEN & CODEINE TABLETS

- This medicine is for the short term treatment of acute moderate pain when other painkillers have not worked.
- You should only take this medicine for a **maximum of 3 days** at a time. If you need to take it for longer than 3 days you should **see your doctor or pharmacist for advice**.
- This medicine **contains codeine** which can **cause addiction** if you take it continuously for **more than 3 days**. This can give you **withdrawal symptoms** from the medicine when you stop taking it.
- If you take this medicine for headaches for **more than 3 days** it can **make them worse**.

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use Solpadeine Migraine Tablets carefully to get the best results from them.

- Keep this leaflet you may need to read it again.
- If you have any further questions, ask your pharmacist.

In this leaflet:

1. What Solpadeine Migraine Does
2. Check before you take Solpadeine Migraine
3. How to take Solpadeine Migraine
4. Possible side effects
5. How to store Solpadeine Migraine
6. Further information

1. What Solpadeine Migraine Does

Solpadeine Migraine can be used in patients **over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers** such as paracetamol or ibuprofen alone.

It can be used for migraine, headaches, period and dental pain, muscle and joint pain, backache, fibrositis, tennis elbow, sports injuries (e.g. sprains, strains) and for pain due to non-serious arthritis.

The active ingredients are ibuprofen and codeine, which are both painkillers. By working on your body in different ways, ibuprofen and codeine combine to relieve pain and ease stiffness. Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which relieve pain and reduce inflammation.

Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers.

2. Check before you take Solpadeine Migraine

- This medicine **contains codeine** which can **cause addiction** if you take it continuously for **more than 3 days**. This can give you **withdrawal symptoms** from the medicine when you stop taking it.
- If you take a painkiller for headaches for **more than 3 days** it can **make them worse**.

Do not take Solpadeine Migraine:

- If you have ever had an allergic reaction to codeine, ibuprofen, aspirin or any other NSAID or to any of the other ingredients (listed in Section 6)
- If you have ever had a **stomach ulcer, perforation or bleeding of the stomach**
- If you are taking **aspirin at doses above 75 mg daily**
- If you are **taking other products containing ibuprofen** or other **NSAID painkillers**
- If you suffer from **severe heart or liver problems**, or **kidney problems**

- If you are **pregnant**.
- For pain relief in children and adolescents (0-18 years of age) after **removal of their tonsils or adenoids** due to **obstructive sleep apnoea syndrome**
- If you know that you **metabolise very rapidly codeine into morphine**
- If you are **breastfeeding**.

Take special care with Solpadeine Migraine

Medicines such as Solpadeine Migraine may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment.

Ask your doctor or pharmacist before you take this medicine:

- If you suffer or have suffered from **asthma or allergic disease**
- If you are **elderly**
- If you suffer from **digestive disease, high blood pressure or autoimmune diseases** such as Lupus
- If you have **heart problems, previous stroke** or think that you might be at risk of these conditions (for example if you have **high blood pressure, high cholesterol** or are a **smoker**)
- If you are taking aspirin at doses below 75 mg
- If you are **trying to become pregnant**
- If you have had an operation to remove your gall bladder or recent stomach surgery
- If you are taking medicines which make you drowsy or sleepy including **sleeping tablets, sedatives, tricyclic antidepressants, tranquillizers e.g. phenothiazine or alcohol**
- If you have been told by your doctor that you have an **intolerance to some sugars**.

If you are taking other medicines

Talk to your doctor or pharmacist before taking these tablets if you are taking any other medicines; particularly drugs to **prevent blood clotting (antiplatelet drugs e.g. aspirin); water tablets (diuretics), MAOIs or lithium** (to treat depression), methotrexate, zidovudine, sulfonyleureas (hypoglycaemic agents), antibiotics (e.g. ciprofloxacin and aminoglycosides such as gentamycin), mifepristone, domperidone, metoclopramide (to treat nausea and vomiting), opiate painkillers, drugs for high blood pressure (e.g. captopril, atenolol or losartan) or corticosteroids (to treat allergic or inflammatory disorders). If you take **blood thinning drugs (anticoagulants e.g. warfarin)** and you need to take a pain reliever on a daily basis, **talk to your doctor** because of the risk of bleeding. But you can still take **occasional** doses of Solpadeine Migraine at the same time as anticoagulants.

Warnings and Precautions

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Children and adolescents

Use in children and adolescents **after surgery**: Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with **breathing problems**: Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Pregnancy and breast feeding

This medicine belongs to a of medicines which may impair fertility in women. This effect goes away when the medicine is stopped. It is unlikely that this medicine, used occasionally, will affect your chances of

becoming pregnant; however tell your doctor before taking this medicine if you have problems becoming pregnant.

Do not take Solpadeine Migraine if you are **pregnant**.

Do not take Solpadeine Migraine while you are **breastfeeding**. Codeine and morphine passes into breast milk.

Driving and using machines

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 if this medicine affects your ability to drive.

However, you would **not** be committing an offence if:


- The medicine has been taken to treat a **medical or dental problem** and
- You have taken it **according to the information provided** with the medicine and
- 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.

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

3. How to take Solpadeine Migraine

This product is intended for short term use only. You should take the lowest effective dose for the shortest time necessary to relieve your symptoms.

-  Adults and children aged 12 years and over:
Swallow 1 or 2 tablets with water, every 4 to 6 hours as needed.

-  • Leave **at least 4 hours between doses**.
- Do not take more than **6 tablets in 24 hours**.
- Do not take **more than the recommended dose**.
- This medicine should not be taken for more than **3 days**. If the pain does not improve after 3 days, **talk to your doctor** for advice.
- Solpadeine Migraine should not be taken by children **below the age of 12 years**, due to the risk of severe breathing problems.

Possible withdrawal effects

This medicine contains codeine and can cause addiction if you take it continuously for **more than 3 days**. When you stop taking it you may get **withdrawal symptoms**. You should **talk to your doctor or pharmacist** if you think you are suffering from withdrawal symptoms.

If you take too many tablets contact your doctor or casualty department. If your symptoms continue or your headache becomes persistent, **see your doctor**.

4. Possible side effects

Some people may have side effects when using this medicine. If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional.

If you suffer from any of the following at any time during treatment **stop taking** the medicine and **seek immediate medical help**:

- Passing blood in your stools
- Passing black tarry stools
- Vomiting any blood or dark particles that look like coffee grounds.

Stop taking the medicine and **tell your doctor** if you experience:

- Allergic reactions, which can include; bruising or facial swelling, swelling of the lips, throat and tongue causing difficulty swallowing or breathing; breathing problems e.g. unexplained wheezing, shortness of breath, asthma or worsening asthma; skin reactions e.g. skin rashes, itching, urticaria (hives) which can be severe with blistering and peeling of the skin; rapid heart rate/palpitations, collapsing or low blood pressure.

- Severe abdominal pain, nausea and vomiting if you have recently had your gall bladder removed.
- Unexplained bruising or bleeding, sore throat, mouth ulcers, fever, extreme paleness, weakness or exhaustion. These can be signs of blood disorders such as anaemia, low white blood cells, low platelet count, suppressed bone marrow function or reduction in agranulocytes (a type of white blood cell).

The following side effects may occur.

Tell your doctor if you get them.

In 1 in 10 to 1 in 100 people:

- Headaches, drowsiness, dizziness, vertigo or ringing in the ears.

In 1 in 100 to 1 in 1000 people:

- Stomach pains, nausea and digestive problems.

In 1 in 1000 to 1 in 10,000 people:

- Diarrhoea, constipation, flatulence or vomiting.

In less than 1 in 10,000 people:

- Worsening of existing bowel disease (ulcerative colitis or Crohn's disease)
- Aseptic meningitis with symptoms such as headache, stiff neck, disorientation, fever and eye sensitivity to light, particularly in patients with existing autoimmune disorders such as lupus.
- Blood in the urine, cloudy urine, you pass more or less urine than normal or you experience pain in the back and/or swelling (particularly in the legs).
- liver problems such as hepatitis or jaundice (yellowing of the skin).
- Breathlessness and/or swelling of the legs or feet.

Medicines such as Solpadeine Migraine may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

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 By reporting side effects you can help provide more information on the safety of this medicine.

How do I know if I am addicted?

If you take this medicine according to the instructions on the pack, it is unlikely you will become addicted to the medicine. However, if the following apply to you it is important that you **talk to your doctor**:

- You need to take the medicine for **longer periods of time**.
- You need to take **more than the recommended dose**.
- When you stop taking the medicine you feel very unwell but you **feel better if you start taking the medicine again**.

5. How to store Solpadeine Migraine

Keep out of the reach and sight of children. Do not use this medicine after the 'EXP' date shown on the pack.

6. Further information

Active ingredients Each tablet contains Ibuprofen 200 mg and Codeine Phosphate Hemihydrate 12.8 mg.
Other ingredients Microcrystalline cellulose, hydrogenated vegetable oil, sodium starch glycolate, colloidal silicon dioxide, lactose, hypromellose, polyethylene glycol.

This pack contains 24 tablets embossed with MIGRAINE or plain on both sides.

The marketing authorisation holder is Omega Pharma Ltd, 32 Vauxhall Bridge Road, London, SW1V 2SA, United Kingdom and all enquiries should be sent to this address.

The manufacturer is GlaxoSmithKline Dungarvan Ltd., Co. Waterford, Ireland or Swiss Caps GmbH Grassingerstraße 9, 83043 Bad Aibling, Germany (Aenova Group).