

## Package leaflet: Information for the user

### Solpadeine Migraine Ibuprofen & Codeine

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- This medicine has been provided to you and should not be given to anyone else
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### What is in this leaflet

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

#### 1. What Solpadeine Migraine Ibuprofen & Codeine Tablets is and what it is used for

Solpadeine Migraine Ibuprofen & Codeine Tablets contains the active ingredients ibuprofen and codeine phosphate hemihydrate, which are both painkillers. 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.

Solpadeine Migraine Ibuprofen & Codeine Tablets can be used in patients **over 12 years** of age for the **short-term relief of acute moderate pain that is not relieved by other painkillers** such as paracetamol or ibuprofen alone. It can be used for migraine, headache, dental pain, period pain, strains & sprains, musculo-tendinitis, backache, non-serious arthritic and rheumatic pain and sciatica.

#### 2. What you need to know before you take Solpadeine Migraine Ibuprofen & Codeine Tablets

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Solpadeine Migraine Ibuprofen & Codeine Tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

#### Do not take Solpadeine Migraine Ibuprofen & Codeine Tablets

- If you are allergic to codeine, ibuprofen, aspirin or any other NSAID or opioid analgesics 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 suffer from **severe heart or severe 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 and/or adenoids** due to obstructive sleep apnoea syndrome.
- If you know that you **metabolise very rapidly codeine into morphine.**
- If you are **breastfeeding.**
- If you suffer from **breathing difficulties or chronic constipation.**

## **Warnings and precautions**

- Do not take this medicine whilst taking any other codeine containing products.
- Do not take this medicine whilst taking any other ibuprofen containing products.
- 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.

### Talk to your doctor or pharmacist before taking this medicine:

- If you suffer or have suffered from asthma or allergic disease.
- If you are elderly.
- If you suffer or ever have suffered from digestive disease.
- If you suffer from 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, diabetes or are a smoker).
- If you are taking aspirin at doses below 75 mg or other blood thinning medicines or corticosteroids.
- If you are trying to become pregnant.
- If you are taking other NSAID painkillers.
- 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 an infection - please see heading "Infections" below.
- If you have impaired liver function.
- If you are dehydrated.
- If you have impaired respiratory function.
- If you have an obstructive bowel disorder or acute abdominal condition.
- If you have hypotension or hypothyroidism.
- If you have experienced a recent head injury or raised intracranial pressure.
- If you have Addison's disease or myasthenia gravis.
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances.

### Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Solpadeine Migraine Ibuprofen & Codeine Tablets:

- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

### **Tolerance, dependence and addiction:**

This medicine **contains codeine** 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 Solpadeine Migraine Ibuprofen & Codeine Tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. If you are taking Solpadeine Migraine Ibuprofen & Codeine Tablets for longer than the recommended time or at higher than recommended doses the risk of side effects can increase and you are also at risk of serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4.).

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 Solpadeine Migraine Ibuprofen & Codeine Tablets 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 Solpadeine Migraine Ibuprofen & Codeine Tablets, 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 might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- 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 Solpadeine Migraine Ibuprofen & Codeine Tablets).

Consult your doctor if your headache becomes persistent. If you take a painkiller for headaches for more than 3 days, it can make them worse.

#### CYP2D6 metabolism:

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.

#### Skin reactions:

Serious skin reactions have been reported in association with Solpadeine Migraine Ibuprofen & Codeine Tablets treatment. You should stop taking this medicine and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

#### Infections:

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

#### Sleep-related breathing disorders

Solpadeine Migraine Ibuprofen & Codeine Tablets 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.

#### **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.

#### **Other medicines and Solpadeine Migraine Ibuprofen & Codeine Tablets**

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

- drugs to prevent blood clotting (antiplatelet drugs e.g. aspirin);
- other NSAIDs (non-steroidal anti-inflammatory drugs);
- water tablets (diuretics);
- MAOIs, SSRIs or lithium (to treat depression);
- methotrexate;
- zidovudine;
- sulfonylureas (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);
- corticosteroids (to treat allergic or inflammatory disorders);
- medicines that make you drowsy or sedated (e.g. benzodiazepines or related medicines, alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressants and psychotics such as phenothiazines);
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve pain (neuropathic pain);
- If you take blood thinning drugs (anticoagulants e.g. warfarin), if 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 Ibuprofen & Codeine at the same time as anticoagulants.
- ciclosporine;
- tacrolimus;
- probenecid or any medication used for the treatment of gout;
- digoxin (used to treat heart arrhythmias) due to a risk of lowering heart rate;
- medicines to treat fungal infections (e.g. fluconazole, sulfapyrazone and voriconazole).

### **Pregnancy and breast feeding**

This medicine belongs to a group of medicines which may impair fertility in women. This effect goes away when use of 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 Ibuprofen & Codeine Tablets if you are **pregnant**.

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

### **Driving and using machines**

This medicine can affect your ability to drive or operate machinery as it may make you feel sleepy or dizzy. Do not drive or use machines while taking this medicine until you know how it affects you. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive or operate machinery while taking this medicine.

It may be an offence to drive if your ability to drive safely is affected. 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](http://www.gov.uk/drug-driving-law)

### **Solpadeine Migraine Ibuprofen & Codeine tablets contains:**

This medicine contains less than 1 mmol sodium (23 mg) per 2 tablets, that is to say essentially 'sodium-free'.

This medicine 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.

### **3. How to take Solpadeine Migraine Ibuprofen & Codeine Tablets**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or

pharmacist if you are not sure.

### **Use in adults**

Swallow 1 or 2 tablets with water, every 4 to 6 hours as needed and up to 3 times a day. Leave at least 4 hours between doses.

Do not take more than **6 tablets in 24 hours**.

### **Use in adolescents and children aged 12 years and over**

Swallow 1 or 2 tablets with water up to 3 times a day. Leave at least six 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. If no effective pain relief is achieved, talk to your doctor for advice.

Solpadeine Migraine Ibuprofen & Codeine should not be taken by children **below the age of 12 years**, due to the risk of severe breathing problems.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Solpadeine Migraine Ibuprofen & Codeine Tablets, 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 Solpadeine Migraine Ibuprofen & Codeine Tablets).

### **If you take more Solpadeine Migraine Ibuprofen & Codeine Tablets than you should**

If you have taken more tablets than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken. The symptoms can include **nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears**, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

### **If you stop taking Solpadeine Migraine Ibuprofen & Codeine Tablets**

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 such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating**. You should **talk to your doctor or pharmacist** if you think you are suffering from withdrawal symptoms.

## **4. Possible side effects**

Like all medicines, Solpadeine Migraine Ibuprofen & Codeine Tablets can cause side effects, although not everybody gets them.

### **Stop taking the medicine and seek urgent medical advice if you experience**

- Passing blood and/or black tarry in your stools;
- Aseptic meningitis symptoms such as headache, stiff neck, disorientation, fever, and eye sensitivity to light, particularly in patients with existing autoimmune disorders such as lupus.
- Sudden inflammation of the pancreas causing severe pain in the belly and back (acute pancreatitis)
- Vomiting any blood or dark particles that look like coffee grounds;
- Liver, kidney problems or difficulty urinating;
- Unexplained bruising or bleeding, sore throat, mouth ulcers, fever, extreme paleness, weakness or exhaustion. These can be signs of blood disorders such as decrease in red blood cells

(anaemia), low white blood cells, low platelet count, suppressed bone marrow function or reduction in agranulocytes (a type of white blood cell).

- 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; chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome;
- Shortness of breath (bronchospasm)
- Severe abdominal pain, nausea and vomiting if you have recently had your gall bladder removed;
- Solpadeine Migraine Ibuprofen & Codeine Tablets, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them from removing acids properly from your blood into the urine (renal tubular acidosis). Signs and symptoms include muscle weakness and light-headedness.
- Skin problems:
  - A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells);  
A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).
  - Life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
  - Life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals (Toxic epidermal necrolysis)
  - Skin becomes sensitive to light.

## Other side effects

Common: may affect up to 1 in 10 people

- Headache
- Drowsiness
- Dizziness
- Hearing disturbance (tinnitus)

Uncommon: may affect up to 1 in 100 people

- Stomach pains, nausea, and digestive problems
- Skin rash
- Hypersensitivity reactions of the skin with hives and itching
- Drug withdrawal syndrome

Rare: may affect up to 1 in 1,000 people

- Diarrhoea, constipation, flatulence, or vomiting.

Very rare: may affect up to 1 in 10,000 people

- Worsening of existing bowel disease (ulcerative colitis or Crohn's disease)
- Inflammation of the pancreas (pancreatitis)
- Inflammation of the oesophagus
- Peptic ulcer
- Mouth irritation
- Inflammation of the stomach lining
- Acute kidney failure
- Liver problems such as hepatitis or jaundice (yellowing of the skin).
- Skin blisters

- Redness of the skin which is usually mild and goes away in a few weeks (erythema multiforme)
- Exacerbation of asthma

Not known: frequency cannot be estimated from the available data

- abnormal accumulation of fluid under the skin
- Decreased appetite
- low blood potassium levels which can cause weakness, muscle cramps, tingling and heart rhythm disturbance
- Small increased risk of arterial thrombotic events
- Drug dependency
- Dry mouth
- Worsening of headache with prolonged use
- Sweating
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

#### **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).

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

#### **5. How to store Solpadeine Migraine Ibuprofen & Codeine Tablets**

Keep this medicine out of the reach and sight of children. Do not use this medicine after the expiry date which is stated on the pack. Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.

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

##### **What Solpadeine Migraine Ibuprofen & Codeine Tablets contains**

**The active substances** are: each tablet contains Ibuprofen 200 mg and Codeine Phosphate Hemihydrate 12.8 mg.

**The other ingredients** are: Microcrystalline cellulose, hydrogenated vegetable oil, sodium starch glycollate, colloidal silicon dioxide, lactose, hypromellose, polyethylene glycol.

##### **What Solpadeine Migraine Ibuprofen & Codeine Tablets looks like and contents of the pack**

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

##### **Marketing Authorisation Holder and Manufacturer**

The marketing authorisation holder is Galpharm Healthcare Limited, Wrafton, Braunton, Devon, EX33 2DL, United Kingdom and all enquiries should be sent to this address.

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

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