

**B. PACKAGE LEAFLET**

## Package leaflet: Information for the user

### ASPESINE 300 mg/250 mg/30 mg tablets Acetylsalicylic acid (Aspirin) /Paracetamol/Caffeine

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or your symptoms worsen or do not improve after 3 days for migraine and 4 days for headache

#### What is in this leaflet

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

#### 1. What ASPESINE is and what it is used for ?

Each tablet of ASPESINE contains three active substances: acetylsalicylic acid (aspirin), paracetamol and caffeine.

- Acetylsalicylic acid (aspirin) and paracetamol reduce pain and fever, and acetylsalicylic acid also reduces inflammation.
- Caffeine is a mild stimulant and increases the effect of acetylsalicylic acid (aspirin) and paracetamol.

ASPESINE is used for the acute treatment of headache and migraine attacks (symptoms such as headache, nausea, sensitivity to light and sound and functional disability) with or without an aura.

#### 2. What you need to know before you take ASPESINE ?

##### Do not take ASPESINE:

- If you are **allergic** (hypersensitive) to **acetylsalicylic acid (aspirin), paracetamol, caffeine or any of the other ingredients of Aspesine** (listed in section 6).  
**Symptoms of an allergic reaction** may include: asthma, wheezing or shortness of breath, skin rash or hives, swelling of the face or tongue, runny nose. In case of any doubt, ask for more information to your doctor or pharmacist.
- If you ever had an allergic reaction to other **medicines used to treat pain, inflammation or fever**, such as diclofenac or ibuprofen.
- If you have a **stomach or intestinal ulcer**, or if you have a **history of peptic ulceration**
- If you noticed **blood in your stools or black stools** (symptom of gastrointestinal bleeding or perforation).
- If you are **haemophilic or suffer from other blood disorders**.
- If you have **serious heart, liver or kidney problems**.
- If you take **more than 15 mg of methotrexate per week** (*see Taking other medicines*).
- If you are in the **last 3 months of pregnancy** (*see Pregnancy, breast-feeding and fertility*).

## Warnings and precautions

ASPESINE contains paracetamol. Do not take more than the recommended dose because it can seriously damage your liver.

Acetylsalicylic acid can cause bleeding. You should tell a doctor if you experience unusual bleeding.

The following are reasons why ASPESINE may not be suitable for you

Talk to your doctor or pharmacist **before** taking ASPESINE if you:

- Have not been diagnosed with migraine before, as potentially serious conditions relating to the brain or nerves need to be excluded before treatment.
- Have a **migraine** that is so severe as to require bed rest, or a headache different from your usual migraines, or if you have **vomiting with your migraine headache**.
- Start having **headaches** after or caused by head injury, exertion, coughing or bending
- Have chronic headaches (15 days or more per month for more than 3 months), or if you experience your first headache after the age of 50.
- Suffer from a **hereditary condition called glucose 6-phosphate dehydrogenase deficiency** that affects the red blood cells and could cause anaemia, jaundice or enlargement of the spleen when exposed to certain foods, medicinal products such as certain anti-inflammatory drugs (e.g., acetylsalicylic acid (aspirin)) or other diseases.
- Have ever had **gastrointestinal problems** such as stomach ulcer, bleeding or black stools. If you have had stomach discomfort or heartburns after taking pain relievers or anti-inflammatory medicines in the past.
- Suffer from bleeding disorders **or abnormal vaginal bleeding** other than your menstrual period (e.g., unusually heavy and prolonged menstrual period).
- Have recently undergone a **surgical operation** (including minor ones such as dental surgery) or will undergo one within the next 7 days.
- Have **bronchial asthma, hay fever, nasal polyps, a chronic respiratory disease, or develop allergic symptoms** (e.g., skin reaction, itching, urticaria).
- Have **gout, diabetes, hyperthyroidism, arrhythmia, uncontrolled hypertension, impaired liver or kidney function**.
- Have **alcohol problems** (see ASPESINE with food, drinks).
- **Are already taking other medicinal products containing acetylsalicylic acid (aspirin) or paracetamol** or other medicines, since certain may interfere with ASPESINE and cause side effects (see Other medicines and ASPESINE).
- Are at risk of being dehydrated (e.g., by vomiting or diarrhoea, or before or after major surgery).
- Are **less than 18 years of age**. There is a possible association between acetylsalicylic acid (aspirin) and Reye's syndrome when given to children and adolescents. Reye's syndrome is a rare disease which affected the brain and liver and can be fatal. For this reason, ASPESINE should not be given to children or adolescents under 18 years unless specifically indicated by your doctor.

## Other precautions

As with any type of painkiller for headaches, taking ASPESINE too often (meaning on more than 10 days per month for this product) with concurrent chronic headaches (15 days per month or more), for more than 3 months, could worsen your headache or migraine. If you think that this may be the case, please contact your doctor for advice. You may need to stop taking ASPESINE to resolve the problem.

ASPESINE may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make it more difficult to detect it. If you feel unwell and you need to see a doctor, remember to tell him or her that you are taking ASPESINE.

ASPESINE may affect the results of laboratory tests. If you have been asked to have blood urine or other laboratory testing, remember to tell that you are taking ASPESINE.

## **Other medicines and ASPESINE**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription,

In particular, tell your doctor if you are taking any of the following medicines:

- **Any other medicinal product that contains paracetamol, acetylsalicylic acid (aspirin) or any other pain reliever/ fever reducer.**
- **Medicines used to prevent blood-clotting** (“blood thinners”) such as oral anticoagulants (e.g., warfarin), heparin, thrombolytics (e.g., streptokinase) or other antiplatelets (ticlopidine, clopidogrel, cilostazole).
- **Corticosteroids** (used to provide relief of inflammation).
- **Barbiturates and benzodiazepines** (to treat anxiety and insomnia).
- **Lithium, selective serotonin reuptake inhibitors or fluvoxamine** (to treat depression).
- **Sulphonylureas and insulin** (to treat diabetes).
- **Methotrexate** (to treat some kinds of cancers, arthritis or psoriasis).
- **some medicines used to treat infection** (e.g., rifampicin, isoniazide, chloramphenicol, ciprofloxacin or piperimidic acid).
- **Levothyroxine** (to treat hypothyroidism).
- **Metoclopramide** (to treat nausea and vomiting).
- **epilepsy medication.**
- high blood pressure and heart failure medication.
- Diuretics (to increase urine production and reduce the excess of fluid).
- **Medicines to treat gout.**
- **Oral contraceptives.**
- **Zidovudine** (to treat HIV).
- Medicines to treat slow gastric emptying such as propantheline.
- **Clozapine** (to treat schizophrenia).
- **Sympathomimetics** (to raise low blood pressure or to treat nasal congestion).
- **antiallergics** (to prevent or relieve allergies).
- **Theophylline** (to treat asthma).
- **Terbinafine** (to treat fungal infections).
- **Cimetidine** (to treat heartburn and peptic ulcers).
- **Disulfiram** (to treat alcohol dependence)
- **Nicotine** (used for smoking cessation).
- **Cholestyramin** (to treat high cholesterol levels).

### **Taking ASPESINE with food, drink and alcohol**

#### **- Alcohol**

If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take this medicine or other pain relievers/fever reducers. Paracetamol and acetylsalicylic acid (aspirin) may cause liver damage and stomach bleeding.

#### **- Caffeine**

The recommended dose of this medicine contains about as much caffeine as a cup of coffee. Limit your intake of caffeine-containing medications, foods or beverage while taking this medicine because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice and do not take ASPESINE. It is especially important not to take ASPESINE during the 3 last months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Do not take ASPESINE if you are breast-feeding as it might be harmful for your infant.

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

ASPESINE belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the treatment.

### **Driving and using machines**

Taking ASPESINE is not known to affect your ability to drive and use machines.

If you notice side effects such as dizziness or drowsiness, you should not drive or use machines. Talk to your doctor as soon as possible.

**ASPESINE contains** methyl paraben (E218), propyl paraben (E216) and colour erythrosine (E127) that may cause allergic reactions (possibly delayed).

## **3. How to take ASPESINE?**

Always take ASPESINE exactly as stated in this package leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

### **Method and route of administration**

Oral administration.

### **Use in adults (18 years of age and older)**

- For headache treatment:  
Take 1 tablet with a full glass of water when headache pain appears. If needed, you can take 1 more tablet 4 to 6 hours later.  
In case of more intense pain, take 2 tablets with a full glass of water when headache pain appears. If needed, you can take another 2 tablets 4 to 6 hours later.
- For migraine treatment  
Take 2 tablets with a full glass of water when the migraine symptoms or migraine aura appears. If needed, you can take an additional 2 tablets, with 4 to 6 hours between doses.  
If you get no migraine relief within 2 hours from the first 2-tablet dose of ASPESINE, you should seek the advice of a doctor.  
Do not use ASPESINE for more than 3 days for a migraine without consulting your doctor.

For both headache and migraine treatment, do not exceed 6 tablets over a period of 24 hours. This corresponds to a dose of 1800 mg of aspirin, 1500 mg of paracetamol and 180 mg of caffeine.

Prolonged use except under medical supervision may be harmful.

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

ASPESINE should not be given to children and adolescents under 18 years of age (*see Warnings and precautions*).

### **Use in elderly patients**

There are no special dosage recommendations. If you have low body weight, you should seek the advice of a doctor or pharmacist.

### **Use in patients with kidney or liver issues**

You should inform your doctor if you have kidney or liver problems. Your doctor may need to adjust the dose interval or the treatment duration. Do not take ASPESINE if you suffer from severe kidney or liver problems.

### **If you take more ASPESINE than you should**

If you have taken too much ASPESINE, contact your doctor or pharmacist immediately.

These tablets contain acetylsalicylic acid (aspirin), paracetamol and caffeine. Do not take more than the recommended dose and do not take any other medicines which may contain either of these ingredients or any other medicines used to treat pain, inflammations or fever (non-steroidal anti-inflammatory drugs) while using ASPESINE.

Contact your doctor, your pharmacist or go to the nearest hospital as soon as you think you might have taken an overdose. Immediate medical attention is critical, because of the potential risk of irreversible liver damage due to paracetamol. Do not wait for symptoms to appear as the overdose might not, at first, produce any noticeable symptoms.

If symptoms of overdose appear they could be:

- For **acetylsalicylic acid** (aspirin): dizziness, ringing in the ears, , deafness, sweating, hyperventilation, fever, nausea, vomiting, headache, confusion or restlessness, circulatory collapse or respiratory failure.
- For **paracetamol**: the first symptoms that may appear are nausea, vomiting, lack of appetite, pallor, sleepiness, sweating and, later, abdominal pain.
- For **caffeine**: anxiety, nervousness, restlessness, insomnia, excitement, muscle twitching, confusion, convulsions, hyperglycaemia, tachycardia or cardiac arrhythmia.

**Even if these symptoms do not appear or if they vanish, it is essential to seek medical help immediately**

#### **If you forget to take ASPESINE**

Take the dose as soon as you remember it, but do not take a double dose to make up for a forgotten dose. Do not take more than 6 tablets over a period of 24 hours.

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

#### **4. Possible side effects**

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

**Stop taking ASPESINE and tell your doctor immediately if you have any of these serious side effects:**

- Allergic reaction with swelling of the face, lips, mouth, tongue or throat. This may cause difficulty in swallowing, wheezing, difficulty in breathing and feelings of tightness in the chest (signs of asthma). You may also have a rash or itching, and experience fainting.
- Skin rash (including hives, itching), skin reddening, blistering of lips, eyes or mouth, skin peeling, sores, mouth ulcers.
- Bleeding of the stomach or intestine, ulcer in stomach or intestine, which may be accompanied by severe stomach pain, bloody or black stools, or blood vomiting. As with all pain relievers and fever reducers, this can happen at any time during the treatment, without prior history, and may be fatal. This side effect is particularly serious in elderly people.
- Yellowing of the skin or eyes (signs of liver failure)
- Light-headedness or dizziness (signs of low blood pressure)
- Irregular heartbeats.
- If you have had breathing problems with acetylsalicylic acid or non-steroidal anti-inflammatory drugs and have a similar reaction with this product.
- Unexplained bleeding or bruising.
- Increased number of nosebleeds or bruises.
- Swelling or water retention.
- Ringing in the ears or temporary loss of hearing.
- Behavioural changes, nausea and vomiting (this could be a sign of Reye's syndrome)

The below side effects have been reported in clinical trials. Tell your doctor if you notice any of these other side effects:

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

- Nervousness, dizziness
- Nauseas, abdominal discomfort

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

- Insomnia, trembling, numbness, headache
- Dry mouth, diarrhoea, vomiting
- fatigue, feeling jittery
- heart rate increased

Rare (may affect up to 1 in 1000 people):

- Sore throat, difficulty in swallowing, numbness or tingling around the mouth, excess of saliva
- decreased appetite, altered taste
- Anxiety, euphoric mood, tension
- Attention disorder, memory loss, altered coordination
- Feeling of pain in the cheeks and forehead
- Eye pain, vision disorder
- Hot flashes, peripheral blood vessels disorders (e.g., in the arms or legs)
- Nose bleeds, slow and shallow breathing, runny nose
- Eructation, flatulence
- Excessive sweating, itching, itchy rash, increased skin sensitivity
- Stiffness in muscles, bones or joints, neck pain, back pain, muscular spasms
- Weakness, chest discomfort

The below side effects have also been reported since the marketing with similar medicines. In general, frequency in post-marketing surveillance cannot be determined precisely; thus it is indicated as “not know”.

restlessness, generally feeling unwell or not normal

- Somnolence, migraine
- Reddening of the skin, rash, very rare cases of severe skin reactions have been reported
- Palpitation, breathlessness, sudden difficulty breathing and feeling of tightness in chest with wheezing or cough (asthma)
- Abdominal pain, stomach discomfort after meals
- Increase liver enzyme
- Swelling and irritation inside the nose
- Kidney problems

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

## **5. How to store ASPESINE?**

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

Do not store above 30 °C, protect from humidity.

Do not use ASPESINE after the expiry date which is stated on the packaging. 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 dispose of medicines no longer required. These measures will help protect the environment.

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

### **What ASPESINE tablet contains**

- The active substances are acetylsalicylic acid (aspirin), paracetamol and caffeine
- The excipients are methyl paraben (E218), propyl paraben (E216), colour erythrosine supra (E127), sodium starch glycolate, maize starch, microcrystalline cellulose, purified talc, colloidal anhydrous silica, stearic acid

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

ASPESINE is a white and pink oblong tablet with a break line on one side

Pouch of 4 tablets in low density polyethylene laminated paper.

### **Marketing Authorisation Holder**

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### **Manufacturer:**

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