

PACKAGE LEAFLET: INFORMATION FOR THE USER

Disprin Direct 300mg Orodispersible Tablets
ASPIRIN (acetylsalicylic acid)

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

1. WHAT DISPRIN DIRECT IS AND WHAT IT IS USED FOR

The ingredient that makes Disprin Direct work (the active ingredient) is Aspirin. Aspirin belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It works to relieve pain and inflammation. Disprin Direct can be used to

- relieve mild to moderate pain (such as headache, toothache and nerve pain)
- reduce temperature and inflammation, such as lower back pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DISPRIN DIRECT

Do not take Disprin Direct if you

- are **allergic** to or have ever had an allergic reaction to aspirin or to other non-steroidal anti-inflammatory drugs or to any of the other ingredients (see section 6). Allergic reactions may include wheeziness, runny nose, itchy skin, rash
- have or have ever had a **stomach ulcer, perforation or bleeding**
- have or have ever had a **bleeding disorder**
- have severe **liver or kidney problems**
- are in the last **three months of your pregnancy**, you must not use higher doses than 100 mg per day (see section “pregnancy, breast-feeding and fertility”)
- are **breast-feeding**
- are under **16 years** of age
- have or have ever had **severe heart failure**

WARNINGS AND PRECAUTIONS

Talk to your doctor or pharmacist before taking if you

- suffer from **tightness in the chest, asthma, nasal polyps, hayfever or allergies.**
- suffer from **liver or kidney problems**
- have a history of **inflammatory bowel disease** (e.g. ulcerative colitis or Crohn’s disease)
- have a history of **peptic ulcers and gastro-oesophageal reflux disease (GORD)**

- are in the **first 6 months of pregnancy**
- are **elderly**. Elderly people are more likely to experience unwanted side-effects with NSAIDs, particularly stomach bleeding & perforation which can be fatal
- have **systemic lupus erythematosus** or mixed connective tissue disease, as there is an increased risk of aseptic meningitis
- are taking medication for or have a history of **hypertension and/or heart failure**
- have **gout**
- have a **surgical procedure scheduled** as treatment should be stopped several days before surgery due to increased bleeding time
- are having **thyroid function tests**
- are taking other non-steroidal anti-inflammatory (NSAID) drugs
- have been told by your doctor that you have a deficiency in glucose-6-phosphate dehydrogenase.

Medicines such as Disprin Direct 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. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes, high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.

Caution should be implemented in patients with a history of other bleeding events.

This product belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping this medicine. Stop taking this medicine and contact your doctor if you experience bleeding from the bowel, perforation of the bowel or ulceration associated with use of NSAIDs.

Other medicines and Disprin Direct

Please tell your doctor or pharmacist before taking Disprin Direct if you are taking or have recently taken any other medicines, including non-prescription medicines;

- to thin the blood/prevent clots e.g. warfarin or heparin
- medicines that also contain aspirin
- to prevent organ transplant rejection e.g. cyclosporine, tacrolimus
- for high blood pressure e.g. diuretics ('water tablets') and ACE-inhibitors
- for pain and inflammation e.g. other non-steroidal anti-inflammatory medicines such as ibuprofen or steroids
- for gout e.g. probenecid or uricosurics
- for cancer or rheumatoid arthritis e.g. methotrexate
- to treat depression e.g. Selective Serotonin Re-uptake Inhibitors (SSRIs)
- to treat mood disorders e.g. lithium
- containing corticosteroids
- oral hypoglycaemic agents (oral medicines to treat diabetes)
- for heart failure e.g. cardiac glycosides
- containing aminoglycosides (a type of antibiotic)
- to treat epilepsy e.g. sodium valproate
- anti-platelet agents
- calcium channel blockers
- varicella vaccine
- certain HIV drugs containing zidovudine
- drugs to treat nausea and vomiting containing metoclopramide or domperidone
- quinolone antibiotics
- carbonic anhydrase inhibitors e.g. acetazolamide
- Mifepristone

- medicines that may interfere with some laboratory tests to measure urine glucose
- metamizole (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.

Pregnancy, breast-feeding and fertility:

If you continue or start treatment with Disprin Direct during pregnancy at the instruction of the physician, then use Disprin Direct as advised by your doctor and do not use a higher dose than is recommended.

Pregnancy – last trimester: Do not take Disprin Direct higher than 100 mg per day if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

If you take Disprin Direct at low doses (up to and including 100 mg per day), you need strict obstetric monitoring as advised by your doctor.

Pregnancy – first and second trimester: You should not take Disprin Direct during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Disprin Direct can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Do not use if you are breast-feeding.

This product belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine.

Important information about Disprin Direct

There is a possible link between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver and can be fatal. For this reason, aspirin should not be given to children and adolescents under 16 years, unless on the advice of a doctor.

3. HOW TO TAKE DISPRIN DIRECT

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For oral use.

Disperses on the tongue without water.

Adults and children 16 years and over: 1-2 tablets. The dose may be repeated every 4-6 hours, if needed. **Do not take more than 12 tablets in 24 hours.**

Elderly: Use with care as elderly patients are more prone to side effects

Liver problems: Patients with liver problems should seek the advice of a doctor before taking this product.

Kidney problems: Patients with kidney problems should seek the advice of a doctor before taking this product.

Do not give to children under 16 years, unless advised by a doctor.

Prolonged use except on medical advice can be harmful.

Do not take Aspirin for more than 3 days in a row. If symptoms persist, speak to your doctor or pharmacist.

If you take more than you should

If you think you have taken too many tablets you should go to your nearest Accident and Emergency Department or contact your doctor immediately. Take this leaflet with you and any packaging to show what you have taken. Symptoms are feeling sick or being sick, restlessness, ringing in the ears, fever, fast breathing, dizziness, abdominal pain, vomiting blood or particles which look like coffee grounds, confusion, disorientation, fits, coma.

If you forget to take

Just carry on with the next dose as normal. Do not take a double dose to make up for missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Disprin Direct can cause side effects, but not everybody gets them.

Stop using the product and contact a doctor immediately if you develop

- difficulty in breathing or sudden constriction of the muscles in the walls of the bronchioles that appear as the features of asthma, chronic bronchitis, anaphylaxis (constriction of the airway)
- heart failure (symptoms include shortness of breath and/or swelling of the feet or legs)
- bleeding in or around the brain
- swelling (oedema) and/or severe rash
- signs of gastrointestinal ulcers or bleeding such as indigestion, flatulence (wind), constipation, abdominal pain, black tarry stools, vomiting blood or particles which look like coffee grounds, peptic ulcer

Other side effects of Disprin Direct may include:

- a rare skin condition called toxic epidermal necrolysis
- skin reactions, itching, fluid build-up in tissue below the skin and in mucous membranes which appear as spots or lumps, blood blisters and occasionally flaking of the skin or rarely changes in skin colour (Steven-Johnson syndrome)
- allergic reactions (may consist of wheeziness, runny nose, itchy skin, rash, asthma, sinus disease with recurrent polyps and sensitivity to acetylsalicylic acid). These are more likely in people sensitive to aspirin
- meningitis that is not caused by a bacterial source (aseptic meningitis)
- high blood pressure (hypertension)
- retaining sodium (salt), retaining fluid
- liver or kidney problems
- aplastic anaemia (symptoms include low platelet counts, low white blood cell count, low count of immature red blood cells and low red blood cells)
- bruising easily or bleeding (thrombocytopenia)
- prolonged bleeding time/impairment of blood clotting ability
- reduction in the number of red blood cells (anaemia), white blood cells (agranulocytosis) and platelets (pancytopenia)
- colitis (a condition which can cause abdominal pain, diarrhoea and bleeding from the bowel) or worsening of inflammatory bowel disease (such as Crohn's Disease)
- increase in uric acid in blood
- fever
- headache & blurred vision
- feeling or being sick, diarrhoea, constipation, stomach pain
- hives
- mouth ulcers

Frequencies of the above side effects are very rare or not known.

Undesirable affects may be minimised by using the lowest effective dose for the shortest duration.

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 HPRA Pharmacovigilance. Website: www.hpra.ie.

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

5. HOW TO STORE DISPRIN DIRECT


Keep out of the sight and reach of children. Do not store above 25°C. Store in the original package. Do not use after the expiry date (EXP) shown on the blister or carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Disprin Direct contains**

Each tablet contains 300mg aspirin (acetylsalicylic acid) as the active ingredient. Each tablet also contains glycine, maize starch, microcrystalline cellulose, purified talc, saccharin and lemon flavour 51124.

What Disprin Direct looks like and pack contents

Disprin Direct are white circular tablets marketed with the “Sword” logo  on one side. Available in packs of 24.

Marketing Authorisation Holder and Manufacturer

PA Holder: Reckitt Benckiser Ireland Limited, 7 Riverwalk, Citywest, Dublin 24, Ireland.

Manufacturer: Reckitt Benckiser Healthcare (UK) Limited, Hull HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

For product enquiries, please telephone (01) 6305429

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