

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Isotretinoin Aurobindo 10 mg, capsules Isotretinoin Aurobindo 20 mg, capsules

isotretinoin

You can contribute by reporting any side effects you may experience.

At the end of section 4, you will read how to do this.

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Isotretinoin Aurobindo and what is it used for?
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### 1. WHAT IS ISOTRETINOIN AUROBINDO AND WHAT IS IT USED FOR?

Isotretinoin Aurobindo contains the active substance isotretinoin - a substance related to vitamin A and belongs to a group of medicines called retinoids (for the treatment of acne).

Isotretinoin Aurobindo is used for the treatment of severe forms of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) in adults and adolescents from 12 years of age only after puberty. You will use this medicine if your acne has not improved with anti-acne treatments, such as antibiotics and skin treatments.

The treatment with this medicine must be supervised by a dermatologist (a doctor specialized in treating skin problems).

### 2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

- If you are pregnant or breastfeeding.
- If there is a chance that you could become pregnant, you must take the precautions described under "Pregnancy Prevention Program" in the section "When should you be extra cautious with this medicine?"

- If you are allergic to isotretinoin, soy, peanuts, or any of the other ingredients in this medicine. You can find these ingredients under point 6.
- If you have liver disease.
- If you have a high level of fat in your blood (e.g., cholesterol or triglycerides).
- If you have a very high level of vitamin A in your body (hypervitaminosis A).
- If you are receiving treatment with tetracyclines (a type of antibiotic) at the same time (see also “Are you using any other medicines?”).

If any of these situations apply to you, return to your doctor before taking this medicine.

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before using this medicine.

- If you have ever had mental disorders, e.g., depression, aggressive tendencies, mood swings, or thoughts of self-harm or suicide. This is because your mood may be affected by taking this medicine.
- If you have persistent pain in your lower back or buttocks during treatment with Isotretinoin Aurobindo, tell your doctor. These complaints may indicate sacroiliitis, a form of inflammatory back pain. Your doctor may stop the treatment with Isotretinoin Aurobindo and refer you to a specialist to treat the inflammatory back pain. Further investigation may be necessary, including imaging methods such as an MRI.

### Pregnancy Prevention Program

Women who are pregnant must not use isotretinoin.

This medicine can cause serious harm to your unborn child (the medicine is teratogenic). It can cause severe abnormalities to the brain, face, ears, eyes, heart, and certain glands (thymus gland and parathyroid gland) of your unborn child. There is also an increased risk of miscarriage. This can occur even if isotretinoin is used for a short period during pregnancy.

- You must not use Isotretinoin Aurobindo if you are pregnant or think you might be pregnant.
- You must not use Isotretinoin Aurobindo if you are breastfeeding. This medicine is likely to pass into breast milk and may harm your baby.
- You must not use Isotretinoin Aurobindo if you become pregnant during the treatment.
- After stopping the treatment, you must not become pregnant for 1 month, as this medicine may still be present in your body.

Women who can become pregnant are prescribed Isotretinoin Aurobindo only under strict conditions due to the risk of birth defects (harmful effects on the unborn child).

These are the conditions:

- Your doctor must explain the risk of harm to your unborn child: you must understand why you must not become pregnant and what you must do to prevent pregnancy.
- You must have discussed the possible means of preventing pregnancy (contraceptives) with your doctor. Your doctor can provide you with information on what to do to prevent pregnancy. Your doctor may refer you to a specialist for advice on contraceptives.

- Before you start the treatment, your doctor will ask you to perform a pregnancy test. The test must show that you are not pregnant at the time you start treatment with Isotretinoin Aurobindo.

Women must use effective contraceptives before, during, and after treatment with Isotretinoin Aurobindo.

- You must agree to use at least one highly reliable contraceptive (for example, an intrauterine device [IUD] or contraceptive implant) or two effective contraceptives that work in different ways (for example, a hormonal contraceptive pill (“the pill”) and a condom). Discuss with your doctor which method is suitable for you.
- You must use a contraceptive for 1 month before starting treatment with this medicine, during the treatment, and for 1 month after stopping the treatment.
- You must use a contraceptive even if you do not have a menstrual period or are currently not sexually active (unless your doctor decides this is not necessary).

Women must agree to perform a pregnancy test before, during, and after treatment with Isotretinoin Aurobindo.

- You must agree to regular check-ups with your doctor, preferably every month.
- You must agree to perform regular pregnancy tests, preferably every month. Because this medicine can remain in your body for 1 month after stopping treatment with Isotretinoin Aurobindo, it is necessary to perform a pregnancy test then as well (unless your doctor decides this is not necessary).
- You must agree to perform additional pregnancy tests at your doctor's request.
- You must not become pregnant during the treatment or 1 month after the treatment, as this medicine may still be present in your body.
- Your doctor will discuss all these points with you using a checklist. This form must be signed by you (or your parent/guardian). This form confirms that you have received the information about the risks and that you will adhere to the conditions.

If you do become pregnant during treatment with Isotretinoin Aurobindo, you must immediately stop using this medicine and contact your doctor. Your doctor may refer you to a specialist for further advice.

If you become pregnant within 1 month after stopping treatment with Isotretinoin Aurobindo, you must contact your doctor. Your doctor may refer you to a specialist for further advice.

Your doctor has written information about pregnancy prevention for users of Isotretinoin Aurobindo that you must be given.

A new prescription is needed for more treatments. Each prescription is only valid for 7 days.

#### Advice for men

Very low amounts of Isotretinoin Aurobindo are found in the semen of men taking isotretinoin, but this is too little to harm the unborn child of their partner. You should never pass your medication to others.

#### Special precautions

- You should never give this medicine to anyone else. Return unused capsules to your pharmacist at the end of the treatment.
- If you are a blood donor, it is important to know that you must not donate blood for 1 month after finishing treatment with Isotretinoin Aurobindo. This is because it can be harmful to an unborn child of a patient who receives your blood.

#### Mental health problems

- You may not notice some changes in your mood and behavior, so it is very important to tell your friends and family that you are taking this medicine. They may notice these changes and help you quickly identify any problems you need to discuss with your doctor.

#### Advice for all patients

- Tell your doctor if you have ever had a mental illness (including depression, suicidal behavior, or psychosis) or if you are taking medications for any of these conditions.
- Serious skin reactions (e.g., Erythema multiforme (EM), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN)) have been reported with the use of isotretinoin. The rash may worsen to widespread blistering or peeling of the skin. You should also look for ulcers in the mouth, throat, nose, genitals, and conjunctivitis (red and swollen eyes).
- In rare cases, Isotretinoin Aurobindo can cause severe allergic reactions, some of which may affect the skin in the form of eczema, hives, and bruising or red patches on the arms and legs. If you have an allergic reaction, stop using Isotretinoin Aurobindo and seek urgent advice from a doctor and tell them you are taking this medicine.
- Reduce intensive training and physical activity. Isotretinoin Aurobindo can cause muscle and joint pain, especially in children and teenagers who engage in heavy physical exertion.
- Isotretinoin has been associated with inflammatory bowel disease. Your doctor will discontinue your isotretinoin treatment if you have severe bloody diarrhea without any history of gastrointestinal disorders.
- Isotretinoin can cause dry eyes, intolerance to contact lenses, and visual problems, including reduced night vision. Cases of dry eyes that did not improve after stopping treatment have been reported. Tell your doctor if you have any of these symptoms. Your doctor may ask you to use lubricating eye ointment or tear replacement therapy. If you use contact lenses and have developed an intolerance to them, you may be advised to wear glasses during treatment. Your doctor may refer you to a specialist for advice if you develop visual problems and you may be asked to stop using Isotretinoin.
- Benign increased intracranial pressure (benign intracranial hypertension) has been reported with the use of Isotretinoin and in some cases where Isotretinoin was used together with tetracyclines (a type of antibiotic). Stop using Isotretinoin and seek urgent advice from your doctor if you develop symptoms such as headache, nausea, vomiting, and visual disturbances. Your doctor may refer you to a specialist to check for swelling of the optic disc in the eye (papilledema).
- Isotretinoin can increase liver enzyme levels. Your doctor will perform blood tests before, during, and after treatment with Isotretinoin to monitor these levels. If they remain high, your doctor may lower your dose or stop you from taking Isotretinoin.

- Isotretinoin usually increases blood fats, such as cholesterol and triglycerides. Your doctor will test these levels before, during, and after treatment with Isotretinoin. It is best not to drink alcoholic beverages during treatment or at least reduce the amount you usually drink. Tell your doctor if you already have high blood fats, diabetes (high blood sugars), are overweight, or have an alcohol addiction. You may need to undergo blood tests more frequently. If your blood fats remain high, your doctor may lower your dose or stop your isotretinoin treatment.
- Tell your doctor if you have kidney problems. Your doctor may start you on a lower dose of Isotretinoin and then increase it to the maximum tolerable dose.
- Tell your doctor if you cannot tolerate certain sugars. Your doctor will not prescribe Isotretinoin if you cannot tolerate fructose or sorbitol.
- Isotretinoin can increase blood sugar levels. In rare cases, people develop diabetes. Your doctor may monitor your blood sugar levels during treatment, especially if you already have diabetes, are overweight, or are an alcoholic.
- Your skin is likely to become dry. Use a moisturizing ointment or cream and a lip balm during treatment. To prevent skin irritation, you should avoid using exfoliating or anti-acne products.
- Avoid too much sun and do not use sunlamps or tanning beds. Your skin may become more sensitive to sunlight. Use a sunscreen with a high protection factor (SPF 15 or higher) before going outside.
- You should not undergo cosmetic skin treatments. Isotretinoin Aurobindo can make your skin more vulnerable. You should not undergo waxing (hair removal), dermabrasion, or laser treatments (removal of calluses or scars) during treatment or for at least 6 months after treatment. This can lead to scarring, skin irritation, or rarely, changes in skin pigmentation.

### Children and young adults

The use of Isotretinoin Aurobindo in children under the age of 12 is not recommended. This is because it is not known whether it is safe and effective in this age group. Use this medicine in adolescents over 12 years only after puberty.

### Are you using any other medicines?

Are you using any other medicines besides Isotretinoin Aurobindo, have you done so recently, or is there a possibility that you will use other medicines in the near future, including herbal remedies and over-the-counter products? Then tell your doctor or pharmacist.

- Do not take vitamin A supplements or tetracyclines (a type of antibiotic), or acne skincare products while using this medicine. It is good to use moisturizers and emollients (skin creams or preparations that prevent moisture loss and have a soothing effect on the skin).
- Avoid using topical keratolytic or exfoliative anti-acne agents while using this medicine.

### Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine.

For more information about contraceptives, pregnancy, and breastfeeding, see section 2 “Pregnancy Prevention Program”.

#### Driving and using machines

During treatment, your vision may be impaired. Sometimes these complaints occur very suddenly. In rare cases, this persisted after the treatment was stopped. Other side effects that are very rare include drowsiness and dizziness. If this happens to you, you should not drive or operate machines.

Isotretinoin Aurobindo contains soybean oil, the dye Cochineal Red A, and sorbitol:

- Soybean oil: Isotretinoin Aurobindo contains oil from soybeans. If you are allergic to peanuts or soybeans, you should not use this medicine.
- Cochineal Red A (E124): this dye can cause allergic reactions.
- Sorbitol (E420): if your doctor has told you that you cannot tolerate certain sugars, consult your doctor before using this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per each 10 mg and 20 mg soft capsule, which means it is essentially “sodium-free”.

### 3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The usual starting dose is 0.5 mg per kilogram of body weight per day (0.5 mg/kg/day). If you weigh 60 kg, your dose usually starts at 30 mg per day.

Take the capsules once or twice daily.

Take them on a full stomach. Swallow the capsules whole with liquid or a mouthful of food.

After a few weeks, your doctor may adjust your dose. This depends on the result with this medicine. For most patients, the dose will be between 0.5 and 1.0 mg/kg/day.

If you think Isotretinoin Aurobindo is too strong or too weak, consult your doctor or pharmacist.

If you have severe kidney problems, the starting dose will be lower (e.g., 10 mg/day), and it will be increased to the maximum tolerable dose. If your body cannot tolerate the recommended dose, you may need a lower dose: this may mean you are treated longer and your acne returns more quickly.

The total treatment duration is generally 16 to 24 weeks. Most patients need one course. After stopping the treatment, improvement may continue for up to 8 weeks. You usually do not start a new course within this period.

In some people, acne may worsen during the first weeks of treatment. It usually improves as the treatment progresses.

Have you taken too much of this medicine?

If you take too many capsules or if someone else accidentally takes your medicine, contact your doctor, pharmacist, or nearest hospital immediately.

Have you forgotten to take this medicine?

If you forgot to take your dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and continue as before. Do not take a double dose (two doses close together) to make up for the missed dose.

Do you have any other questions about the use of this medicine? Contact your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them. Some of the side effects associated with the use of isotretinoin are dose-related. The side effects are generally reversible after changing the dose or stopping the treatment, but some may continue after the treatment has stopped. Some side effects can be serious; you should contact your doctor immediately.

Side effects requiring immediate medical attention:

Skin problems

Frequency not known (frequency cannot be estimated from the available data)

- Severe skin rash (erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), which may be life-threatening and requires immediate medical care. It initially appears as round spots, often with central blisters, usually on arms and hands or legs and feet, more severe skin rash may include blisters on the chest and back. Additional symptoms such as eye infection (conjunctivitis) or sores in the mouth, throat, and nose may occur. Severe forms of skin rash can further develop into widespread skin detachment, which can be life-threatening. This severe skin rash is often preceded by headache, fever, body aches (flu-like symptoms).

If you develop a severe skin rash or when these skin symptoms occur, stop taking Isotretinoin Aurobindo and contact your doctor immediately.

Mental problems

Rare side effects (may affect up to 1 in 1,000 people)

- Depression or related disorders, for example with a sad mood or mood swings, anxiety, feeling of emotional discomfort.
- Worsening of existing depression.
- Violent or aggressive behavior.

Very rare side effects (may affect less than 1 in 10,000 people)

- Some people have had thoughts or feelings of self-harm or suicide, have attempted suicide, or have committed suicide, and these people did not seem to be depressed.
- Abnormal behavior.

- Symptoms of psychosis: disturbed contact with reality, such as hearing voices or seeing things that are not there.

Contact your doctor immediately if you experience signs of these psychological symptoms. Your doctor may then advise you to stop taking this medicine, but this may not be enough to stop the side effects: you may need more help and your doctor can arrange that for you.

#### Allergic reactions

Rare side effects (may affect up to 1 in 1,000 people)

- Severe (anaphylactic) reactions: difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips, and mouth. Also sudden swelling of the hands, feet, and ankles.

Very rare side effects (may affect less than 1 in 10,000 people)

- Sudden tightness in the chest, shortness of breath, and wheezing, especially if you have asthma.

If you experience a severe reaction, you must seek medical help immediately.

If you have an allergic reaction, stop taking this medicine and contact your doctor.

#### Bones and muscles

Frequency not known (frequency cannot be determined from the available data)

- Muscle weakness that may be life-threatening can be associated with difficulty moving arms or legs, painful, swollen, bruised areas of the body, dark-colored urine, reduced or no urine output, confusion, or dehydration. These are signs of rhabdomyolysis, a breakdown of muscle tissue that can lead to kidney failure. This can occur if you engage in intense physical exercise while using this medicine.
- Sacroiliitis, a form of inflammatory back pain that can cause pain in your buttocks or lower back.

#### Liver and kidney problems

Very rare side effects (may affect up to 1 in 10,000 people)

- Yellow skin or eyes, feeling tired. These may be signs of hepatitis.
- Stop using this medicine immediately and contact your doctor.
- Problems urinating, swollen and puffy eyelids, feeling excessively tired. These may be signs of a kidney inflammation.
- Stop using this medicine immediately and contact your doctor.

#### Nervous system problems

Very rare side effects (may affect up to 1 in 10,000 people)

- Persistent headache, nausea (vomiting), and changes in your vision, including blurred vision. These may be signs of benign intracranial hypertension, especially if this medicine is taken with antibiotics called tetracyclines. Stop using this medicine immediately and contact your doctor.

#### Intestinal and stomach problems

Very rare side effects (may affect up to 1 in 10,000 people)

- Severe abdominal pain, with or without severe bloody diarrhea, feeling sick (nausea), and being sick (vomiting). These may be signs of serious bowel conditions. Stop using this medicine immediately and contact your doctor.

#### Eye disorders

Very rare side effects (may affect up to 1 in 10,000 people)

- Blurred vision.

If you experience blurred vision, stop taking this medicine immediately and contact your doctor. If your vision is affected in any other way, inform your doctor as soon as possible.

#### Other side effects:

Very common side effects (may affect more than 1 in 10 people)

- Dryness of the skin, especially of the lips and face; inflamed skin, cracked and inflamed lips, rash, mild itching, and mild peeling. Use a moisturizer from the start of the treatment.
- The skin becomes more fragile and redder than usual, especially the face.
- Back pain; muscle pain; joint pain, especially in children and teenagers. To prevent bone or muscle problems from worsening, you should be less physically active while using isotretinoin.
- Inflammation of the eye (conjunctivitis) and eyelid area; eyes feel dry and irritated. Ask a pharmacist for suitable eye drops. If you get dry eyes and wear contact lenses, you may need to wear glasses instead.
- Increased liver enzymes, observed in blood tests.
- Altered blood fat levels (including HDL or triglycerides).
- Bruising, bleeding, or altered clotting (when clotting cells are affected).
- Anemia, weakness, dizziness, and pale skin (when red blood cells are affected).

Common side effects (may affect up to 1 in 10 people)

- Headache.
- Higher cholesterol levels in the blood.
- Proteins or blood in the urine.
- More susceptible to infections if the white blood cells are affected.
- The inside of the nose becomes dry and crusted, which can cause mild nosebleeds.
- Painful or inflamed throat and nose.
- Allergic reactions such as rash, itching. If you have an allergic reaction, stop taking this medicine and contact your doctor.

Rare side effects (may occur in up to 1 in 1,000 people)

- Hair loss (alopecia). This is usually only temporary. Your hair should return to normal after the treatment is finished.

Very rare side effects (may occur in less than 1 in 10,000 people)

- You see less well at night; color blindness worsens and color vision deteriorates.
- Sensitivity to light may increase; you may find that you need to wear sunglasses to protect your eyes from too bright sunlight.
- Other vision problems, including blurred vision, distorted vision, cloudy eye surface (cataract, corneal clouding).

- Extreme thirst; frequent urination; blood tests show an increase in your blood sugar levels. These can all be signs of diabetes.
- Acne may worsen in the first few weeks, but the symptoms should improve over time.
- Skin inflamed, swollen, and darker than normal, especially on the face.
- Excessive sweating or itching.
- Joint inflammation (arthritis); bone disorders (delayed growth, extra growth, and changes in bone density); growing bones may stop growing.
- Calcium deposits in soft tissue, painful tendons, high levels of muscle breakdown products in your blood if you exercise vigorously.
- Increased sensitivity to light.
- Bacterial infections at the base of the nail, changes to the nail.
- Swelling, discharge, pus.
- Thickened scars after surgery.
- Increased body hair.
- Seizures (convulsions), drowsiness, dizziness.
- Lymph nodes may swell.
- Hoarseness, dry throat.
- Hearing problems.
- Feeling unwell.
- High levels of uric acid in the blood.
- Bacterial infections.
- Inflammation of the blood vessels (sometimes with bruising, red spots).

Frequency not known (frequency cannot be determined from the available data)

- Dark or cola-colored urine.
- Problems getting or maintaining an erection.
- Lower libido.
- Breast enlargement in men, with or without tenderness.
- Vaginal dryness.
- Inflammation of the urethra.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store in the original package.

Do not use this medicine after the expiry date. This can be found on the packaging and on the blister strip after "Exp.". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not end up in the environment.

## 6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is respectively 10 mg and 20 mg isotretinoin per capsule.

The other substances in this medicine are:

Capsule core: soybean oil, DL-alpha-tocopherol (E307a), disodium edetate, butylated hydroxyanisole (E320), vegetable oils, and yellow beeswax.

Capsule shell: gelatin, glycerol, sorbitol (E420), purified water. Colorants of the capsule shell: 10 mg: cochineal red A (E124), black iron oxide (E172), titanium dioxide (E171). 20 mg: cochineal red A (E124), indigotine (E132), titanium dioxide (E171).

What does Isotretinoin Aurobindo look like and how much is in a package?

Isotretinoin Aurobindo 10 mg capsules are light purple in color, oval, and contain a yellow-orange cloudy liquid.

Isotretinoin Aurobindo 20 mg capsules are chestnut brown in color, oval, and contain a yellow-orange cloudy liquid.

The packages contain 20, 30, 50, 60, 90, or 100 soft capsules. Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn

Manufacturer:

- Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn, Netherlands

Registered in the register

Isotretinoin Aurobindo 10 mg and 20 mg capsules are registered in the register under RVG 27577 and 27578 respectively.

This medicine is registered in EU member states under the following names:

Portugal: Isotretinoin Aurovitas

Netherlands: Isotretinoin Aurobindo 10 mg and 20 mg, capsules

This leaflet was last approved in January 2024

Detailed and updated information about this medicine is available by scanning the QR code with a QR reader, an application (app) for smartphone or tablet.

The same current information about the medicine is also available via the following URL and on the website of the Medicines Evaluation Board ([www.geneesmiddeleninformatiebank.nl](http://www.geneesmiddeleninformatiebank.nl)).