Package leaflet: Information for the user

Salvacyl
11.25 mg powder and solvent for prolonged-release suspension for injection
triptorelin

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

1. What Salvacyl is and what it is used for

Salvacyl contains triptorelin, which is similar to a hormone called gonadotropin releasing hormone (GnRH analogue). It is a long acting formulation designed to slowly deliver 11.25 mg of triptorelin over twelve weeks. It acts by lowering the levels of the male hormone, testosterone, in the body.

Salvacyl is used to decrease sexual drive in adult men with severe sexual deviations.

The treatment with Salvacyl is to be initiated and controlled by a psychiatrist. The treatment should be given in combination with psychotherapy, in order to decrease deviating sexual behaviour.

2. What you need to know before you use Salvacyl

Do not use Salvacyl
- If you suffer from serious osteoporosis (a condition that weakens your bones).
- If you are allergic to triptorelin, other medicines that regulate the production and release of sex hormones, or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions
At the beginning of treatment there will be an increased amount of testosterone in your body. This might result in an increase in sexual drive. Your doctor may give you some medicine (an anti-androgen) to counteract this effect.

Talk to your doctor:

- If you develop a depressed mood while taking Salvacyl. There have been reports of depression in patients taking Salvacyl which may be severe. Your doctor may want to monitor your depression during your treatment.
- If you are using anticoagulants (medicines that inhibit the blood clotting ability), since you may experience bruises at the site of injection.
- If you are a heavy drinker, a smoker, have osteoporosis (a condition that weakens your bones) or have a family history of osteoporosis, have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids. When Salvacyl is used for a long period of time the risk of developing weak bones is increased, especially if any of the above applies. In order to prevent brittleness of the bones, a healthy lifestyle including no smoking, moderation of alcohol consumption and regular weight bearing exercises that put a load on and strengthens the skeleton, is recommended (e.g. walking, jogging, other forms of sports that put a load on the skeleton). Adequate dietary calcium and vitamin D intake should also be maintained.
- If you are about to take a diagnostic test of pituitary gonadal function or sex organs. The result can be misleading if you are on Salvacyl treatment or after discontinuation of Salvacyl treatment.
- If you experience sudden headache, vomiting, problems with eyesight and paralysis of the eye muscles. These can be signs of a benign tumour of the pituitary gland which may be discovered following treatment with Salvacyl.
- If you have diabetes.
- If you suffer from heart or vascular problems.
- If you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Salvacyl.
- Testosterone decreasing agents may cause changes in ECG associated with heart rhythm abnormalities (QT prolongation).
- Treatment with GnRH analogues including Salvacyl might increase the risk of anaemia (defined as a decrease in the count of red blood cells).

When the treatment is stopped, testosterone will return to normal levels and your sexual drive may increase again. Therefore, your doctor may give you another medicine in order to control this effect.

Children and adolescents
Salvacyl is not indicated for use in neonates, infants, children and adolescents.

Other medicines and Salvacyl
When Salvacyl is taken with medicines which affect the release of hormones from the pituitary (part of the brain), your doctor may need to do additional checks.

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

Salvacyl might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Pregnancy, breast-feeding and fertility
Salvacyl is not to be used by women.

Driving and using machines
You may feel dizzy, tired or have problems with your sight such as blurred vision. These are possible side effects of treatment. If you experience any of these side effects you should not drive or use machines.

Salvacyl contains sodium
This medicinal product contains sodium but less than 1 mmol (23 mg) sodium per vial. This medicine is almost 'sodium-free' and may be taken with a low sodium diet.

3. How to use Salvacyl

Salvacyl is prepared by and is always given to you by a doctor or nurse.
The usual dose is 11.25 mg (one vial) of Salvacyl, given as a single injection into a muscle every twelve weeks.
If you think the effect of Salvacyl is too strong or too weak, contact your doctor.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Many of the side effects are expected, due to the change in the level of testosterone in your body. These effects include hot flushes and impotence.

In rare cases (may affect up to 1 in 1,000 people) you may experience a severe allergic reaction.and commonly (may affect up to 1 in 10 people) you may experience an allergic reaction. Stop taking Salvacyl and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms swallowing or breathing problems, swelling of your lips, face, throat or tongue, or a rash.

Other side effects that may occur

Very common: may affect more than 1 in 10 people
- Hot flushes
- Weakness
- Excessive sweating
- Back pain
- Pins and needles sensation in the legs
- Reduced libido
- Impotence

Common: may affect up to 1 in 10 people
- Nausea, dry mouth
- Pain, bruising, redness and swelling at injection site, muscle and bone pain; pain in the arms and legs; oedema (build up of fluid in the body tissues), lower abdominal pain,
- Allergic reaction
- High blood pressure
- Increase in weight
- Dizziness, headache

- Loss of libido, depression, mood changes

Uncommon: may affect up to 1 in 100 people
- Increase in blood platelet count
- Feeling your heartbeat
- Ringing in the ears, vertigo (sensation of spinning or whirling motion),
- Blurred vision
- Pain in abdomen, constipation, diarrhoea, vomiting
- Drowsiness, severe shivering associated with sweating and a fever, sleepiness, pain
- Some blood tests affected (including raised liver function tests),
- Blood pressure increased
- Weight loss
- Loss of appetite, increase of appetite, gout (severe pain and swelling in the joints usually in the big toe), diabetes, excessive lipids in the blood
- Joint pain, muscle cramps, muscle weakness, muscle pain, swelling and tenderness, bone pain
- Tingling or numbness
- Inability to sleep, irritability
- Development of enlarged breasts, breast pain, reduction in testicular size, pain in the testicles
- Difficulty in breathing
- Acne, hair loss, itching, rash, redness of skin, hives
- The need to wake up to pass urine, problems passing urine
- Nosebleeds

Rare: may affect up to 1 in 1,000 people
- Red or purple discolorations on the skin
- Abnormal sensation in the eye, or disturbance in vision
- Distended abdomen (sensation of fullness in the stomach), flatulence, abnormal sense of taste
- Chest pain
- Difficulty in standing
- Flu-like illness, fever
- Inflammation of the nose/throat
- Increase in an enzyme present in your body such as bone and liver
- Increased body temperature
- Stiff joints, joint swelling, musculoskeletal stiffness, osteoarthritis
- Memory impairment
- Feeling confused, decreased activity, having a feeling of elation or well-being
- Shortness of breath when lying flat
- Blisters
- Low blood pressure

Not known: frequency cannot be estimated from the available data
- Changes in ECG (QT prolongation)
- General discomfort
- Anxiety
- Urinary incontinence
- If an existing pituitary tumour, an increased risk of bleeding to the area
- Anaemia (decrease in the count of red blood cells)

An increase in white blood cell count may be found, as with other GnRH analogues, in patients being treated with Salvacyl.

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 Salvacyl

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

Do not use this medicine after the expiry date which is stated on the carton, vial and ampoule after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Salvacyl contains
The active substance is triptorelin
One vial of powder contains 11.25 mg of triptorelin, as triptorelin embonate.
Reconstituted suspension (2 ml) contains 11.25 mg of triptorelin, as triptorelin embonate.

The other ingredients are:
Powder : poly (d, l-lactide-co-glycolide), mannitol, carmellose sodium and polysorbate 80.
Solvent: water for injection.

What Salvacyl looks like and contents of the package
Salvacyl is a white to off-white powder.
The solvent is a clear solution.

The package contains:
1 vial with powder
1 ampoule with 2 ml of solvent
1 injection syringe
2 needles.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Ipsen Pharmaceuticals Ltd.
Blanchardstown Industrial Park
Blanchardstown
Dublin 15
Ireland.

Manufacturer
Ipsen Pharma Biotech
Parc d' Activité du Plateau de signes
Chemin Départemental n˚ 402
83870 Signes
France.

This medicinal product is authorised in the Member States of the EEA under the following names:
Sweden: Moapar 11.25 mg
Belgium, Germany, Denmark, Finland, Netherlands, United Kingdom, Austria, Ireland, Poland and Greece: Salvacyl 11.25 mg
France: Salvacyl LP
Norway: Salvapar

Is this leaflet hard to see or read? Please phone +353 1 809 8256 and ask for help.

This leaflet was last revised in January 2025

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The following information is intended for healthcare professionals only (please see section 3):

1 – PREPARATION OF THE PATIENT BEFORE RECONSTITUTION

- Prepare the patient by disinfecting his gluteus at the injection site. This operation needs to be performed first because once reconstituted, the drug should be injected immediately.

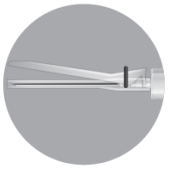
2 – PREPARATION OF THE INJECTION

Two needles are provided in the box :

- **Needle 1** : a 20G needle (38mm of length) without safety device to be used for reconstitution
- **Needle 2** : a 20G needle (38mm of length) with safety device to be used for injection

needle 1 - 38 mm

needle 2 - 38 mm



The presence of bubbles on top of the lyophilisate is a normal appearance of the product.
The following steps must be completed in a continuous sequence.

2a

- Take out the ampoule containing the solvent. Tap any solution within the tip of the ampoule back to the main body of the ampoule.
- Screw Needle 1 (without safety device) on to the syringe. Do not remove the needle protection yet.
- Break open the ampoule with dot face up.
- Remove the needle protection from Needle 1. Insert the needle in the ampoule and draw up all the solvent into the syringe.
- Put aside the syringe containing the solvent.

2b

- Take out the vial containing the powder; tap any powder which has accumulated at the top of the vial back to the bottom of the vial.
- Remove the plastic tab on the top of vial.
- Take back the syringe containing the solvent and insert the needle through the rubber stopper vertically into the vial. Inject the solvent slowly, so that, if possible, it washes down the entire upper part of the vial.

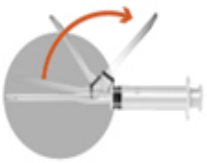
2c

- Pull up Needle 1 above the liquid level. Do not remove the needle from the vial. Reconstitute the suspension by swirling gently from side to side. Do not invert the vial.
- Make sure that the agitation is long enough (at least 30 seconds) to obtain a homogeneous and milky suspension.
- **Important: Check there is no unsuspended powder in the vial (if any powder clumps are present, continue swirling until they disappear).**

2d

- When the suspension is homogeneous, pull down the needle without inverting the vial, draw up all of the suspension. A small amount will remain in the vial and should be discarded. An overage is included to allow for this loss.

- Grasp the coloured hub to disconnect the needle. Remove Needle 1 used for the reconstitution from the syringe. Screw on to the syringe Needle 2.
- Move the safety sheath away from the needle and towards the syringe barrel. The safety sheath remains in the position you set.
- Remove the needle protection from the needle.
- Prime the needle to remove air from the syringe and inject immediately.



3- INTRAMUSCULAR INJECTION

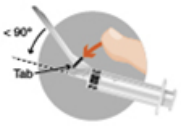
- To avoid sedimentation, inject immediately into the disinfected area as quickly as possible (within 1 minute from reconstitution).

4 – AFTER USE

- Activation of the safety system using a one-handed technique.
- Note: Keep your finger behind the tab at all times.

There are two alternatives to activate the safety system:

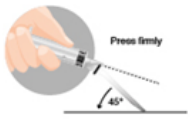
- Method A : push the tab forward with your finger



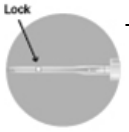
or

- Method B : push the sheath to a flat surface.

or



- In both cases press down with a firm quick motion until a distinct audible click is heard.
- Visually confirm that the needle is fully engaged under the lock.



• Used needles, any unused suspension or other waste material should be disposed of in accordance with local requirements.	