11.08.2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

INTAZA 150

Azacitidine 150 mg

Powder for suspension for injection

Contains sugar: Each vial contains 150 mg mannitol

Read all of this leaflet carefully before you are given INTAZA 150

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What INTAZA 150 is and what it is used for

INTAZA 150 belongs to a group of medicines called “cytotoxics”.

INTAZA 150 is an anti-cancer medicine used to treat certain cancers of the bone marrow.

2. What you need to know before you are given INTAZA 150

11.08.2025

PATIENT INFORMATION LEAFLET

INTAZA 150 should not be given to you:

- if you are allergic to azacitidine or to any of the other ingredients of INTAZA 150 listed in section 6.1
- if you have advanced liver cancer
- if you have severe kidney damage
- if you are pregnant or breastfeeding your baby
- if you are younger than 18 years old

Warnings and precautions

Special care should be taken with INTAZA 150:

- if you have kidney disease
- if you have liver disease

You will have blood tests before you begin treatment with INTAZA 150 and at the start of each period of treatment (called a 'cycle'). This is to check that you have enough blood cells and that your liver and kidneys are working properly.

- If you have heart disease.
- If you have lung disease.
- If you develop blisters, redness or painful areas and swelling on your skin, inform your doctor. You may have developed a rare bacterial infection called necrotising fasciitis.
- If you experience dark urine, muscle spasms or cramps, numbness, seizures or hallucinations, inform your doctor. A rare syndrome called Tumour lysis may have occurred.

Children and adolescents

INTAZA 150 is not indicated in children and adolescents below the age of 18.

11.08.2025

PATIENT INFORMATION LEAFLET

Other medicines and INTAZA 150

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please consult your doctor, pharmacist or other healthcare professional for advice.

This is because INTAZA 150 may affect the way some other medicines work. Also, some other medicines may affect the way INTAZA 150 works.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor or pharmacist for further advice before taking INTAZA 150.

Pregnancy

You should not receive INTAZA 150 if you are pregnant.

Breast-feeding

You must discontinue breastfeeding whilst receiving your treatment.

Fertility

If you are a man, you should not father a child while receiving INTAZA 150. You should use an effective method of contraception before receiving INTAZA 150.

Women and men of child bearing age should continue to use an effective contraception during and up to 3 months after treatment has been stopped.

Driving and using machines

INTAZA 150 may cause blurred vision, sleepiness or tiredness. If you experience any of these side effects, do not drive or operate machinery.

3. How INTAZA 150 is given

11.08.2025

PATIENT INFORMATION LEAFLET

You will not be expected to give INTAZA 150 to yourself.

It will be given to you by a person who is qualified to do so.

INTAZA 150 will be given to you as a subcutaneous injection (injection into your thigh, abdomen or upper arm a muscle under your skin).

Your doctor will tell you how long your treatment with INTAZA 150 will last.

Do not stop treatment early because it may affect the working of INTAZA 150 in treating your cancer.

If you have the impression that the effect of INTAZA 150 is too strong or too weak, tell your doctor or pharmacist.

If you receive more INTAZA 150 than you should

Since a healthcare professional will administer INTAZA 150, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

INTAZA 150 can have side effects.

Not all side effects for INTAZA 150 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving INTAZA 150, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving INTAZA 150 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat which may be due to an allergic reaction and cause difficulty in swallowing or breathing
- Painful rash, red or peeling skin
- Drowsiness, shaking, jaundice, abdominal bloating and easy bruising. These may be symptoms of liver

failure and can be life-threatening.

- Swelling of the legs and feet, back pain, reduced passing of water, increased thirst, rapid pulse, dizziness and nausea, vomiting or reduced appetite and feelings of confusion, restlessness or fatigue. These may be symptoms of kidney failure and can be life-threatening
- A fever. This could be due to an infection as a result of having low levels of white blood cells, which can be life-threatening.
- Chest pain or shortness of breath which may be accompanied with a fever. This may be due to an infection of the lung called “pneumonia”, and can be life-threatening.
- Bleeding. Such as blood in the stools due to bleeding in the stomach or gut, or such as bleeding inside your head. These may be symptoms of having low levels of platelets in your blood.

These are all very serious side effects. If you have them, you may have had a serious reaction to INTAZA 150. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain (angina)
- difficulty breathing

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Reduced red blood count (anaemia). You may feel tired and pale
- Reduced white blood cell count. This may be accompanied by a fever. You are also more likely to get infections
- A low blood platelet count (thrombocytopenia). You are more prone to bleeding and bruising

- Constipation, diarrhoea, nausea, vomiting
- Pneumonia
- Chest pain, being short of breath
- Tiredness (fatigue)
- Injection site reaction including redness, pain or a skin reaction
- Loss of appetite
- Joint aches
- Bruising
- Rash
- Red or purple spots under your skin
- Pain in your belly (abdominal pain)
- Itching
- Fever
- Sore nose and throat, stuffy nose
- Dizziness
- Headache
- Having trouble sleeping (insomnia)
- Nosebleeds (epistaxis)
- Muscle aches
- Weakness (asthenia)
- Weight loss
- Low levels of potassium in your blood
- Bleeding inside your head
- An infection of the blood caused by bacteria (sepsis). This may be due to low levels of white cells in your blood.

- Bone marrow failure. This can cause low levels of red and white blood cells and platelets
- A type of anaemia where your red and white blood cells and platelets are reduced
- An infection in your urine.
- A viral infection causing cold sores (herpes).
- Bleeding gums, bleeding in the stomach or gut, bleeding from around your back passage due to piles (haemorrhoidal haemorrhage), bleeding in your eye, bleeding under your skin, or into your skin (haematoma).
- Blood in your urine
- Ulcers of your mouth or tongue.
- Changes to your skin at the injection site. These include swelling, a hard lump, bruising, bleeding into your skin (haematoma), rash, itching and changes in the skin colour.
- Redness of your skin
- Skin infection (cellulitis).
- An infection of the nose and throat, or sore throat
- Sore or runny nose or sinuses (sinusitis)
- High or low blood pressure (hypertension or hypotension).
- Being short of breath when you move
- Pain in your throat and voicebox
- Indigestion
- Lethargy
- Feeling generally unwell
- Anxiety
- Being confused
- Hair loss
- Kidney failure

- Dehydration
- White coating covering tongue, inner cheeks, and sometimes on the roof of your mouth, gums and tonsils (oral fungal infection).
- Fainting
- A fall in blood pressure when standing (orthostatic hypotension) leading to dizziness when moving to a standing or sitting position.
- Sleepiness, drowsiness (somnolence).
- Bleeding due to a catheter line
- A disease affecting the gut which can result in fever, vomiting and stomach pain (diverticulitis)
- Fluid around the lungs (pleural effusion).
- Shivering (chills)
- Muscle spasms
- Raised itchy rash on the skin (urticaria).
- Collection of fluid around the heart (pericardial effusion).
- Loss of feeling or numbness in any part of your body.
- Increased sweating.

Less frequent

- Allergic (hypersensitivity) reaction.
- Liver failure
- Large plum-coloured, raised painful patches on the skin with fever.
- Painful skin ulceration (pyoderma gangrenosum)
- Inflammation of the lining around the heart (pericarditis).
- Tumour lysis syndrome - Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the product of dying cancer

cells and may include the following: changes to blood chemistry; high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heartbeat, seizures, and sometimes death.

- Anal pain, constipation, fever might indicate the formation of an abscess around the anus.

Frequency unknown

- Infection of the deeper layers of skin, which spreads quickly, damaging the skin and tissue, which can be life-threatening (necrotizing fasciitis).
- Weakness in hands and legs, loss of memory, loss of vision, headache – may indicate damage to your nervous system, i.e. your brain and spinal cord.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.
By reporting side effects, you can help provide more information on the safety of INTAZA 150.

5. How to store INTAZA 150

Unopened vials:

3 years.

After reconstitution:

11.08.2025

PATIENT INFORMATION LEAFLET

From a microbiological point of view, the medicine 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 8 hours when stored between 2 and 8 °C.

If administration is to be delayed, the reconstituted product may be kept in the vial or drawn into a syringe.

The product must be refrigerated (2 °C - 8 °C) immediately. After removal from refrigerated conditions, the suspension may be allowed to equilibrate to room temperature (25 °C) for up to 30 minutes prior to administration.

When stored at 25 °C, the reconstituted product should be administered within 1 hour.

Keep out of reach of children.

Store in original package until use.

Do not use after the expiry date stated on the label

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What INTAZA 150 contains

- The active substance is azacitidine.
- Each vial contains 150 mg azacitidine.
- The other ingredients are mannitol and water for injection

What INTAZA 150 looks like and contents of the pack

- A white lyophilised powder or cake
- 50 ml Type I clear moulded glass vial with 20 mm grey siliconised westar rubber stopper and 20 mm white aluminium flip off white seal or 20 mm white aluminum flip off white plain seal.

HOLDER OF CERTIFICATE OF REGISTRATION

11.08.2025

PATIENT INFORMATION LEAFLET

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