AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS:

S4

INTAZA 100 (Lyophilised powder for suspension for injection)

Azacitidine

Contains sugar: Each vial contains 100 mg mannitol

Read all of this leaflet carefully before you are given INTAZA 100

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

What is in this leaflet

1. What INTAZA 100 is and what it is used for
2. What you need to know before you are given INTAZA 100
3. How INTAZA 100 will be given to you
4. Possible side effects
5. How to store INTAZA 100
6. Contents of the pack and other information

1. WHAT INTAZA 100 IS AND WHAT IT IS USED FOR

INTAZA 100 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 100

You should not receive INTAZA 100:

- if you are hypersensitive (allergic) to azacitidine or any of the other ingredients of **INTAZA 100** (see

section 6),

- 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

Tell your doctor or healthcare professional before you receive INTAZA 100:

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

You will have blood tests before you begin treatment with **INTAZA 100** 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.

INTAZA 100

Other medicines and INTAZA 100:

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

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

This is because **INTAZA 100** may affect the way some other medicines work. Also, some other medicines may affect the way **INTAZA 100** works.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before you receive **INTAZA 100**.

You should not receive **INTAZA 100** if you are pregnant or breastfeeding your baby.

If you are a man, you should not father a child while receiving **INTAZA 100**. You should use an effective

method of contraception before receiving **INTAZA 100**.

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

3. HOW TO RECEIVE INTAZA 100

Do not share medicines prescribed for you with any other person.

You will not be expected to give **INTAZA 100** to yourself. It will be given to you by a person who is qualified to do so.

INTAZA 100 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 100** will last. Do not stop treatment early because it may affect the working of **INTAZA 100** in treating your cancer.

If you have the impression that the effect of **INTAZA 100** is too strong or too weak, tell your doctor or pharmacist.

If you receive more INTAZA 100 than you should:

Since a healthcare professional will administer **INTAZA 100**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. POSSIBLE SIDE EFFECTS

INTAZA 100 can have side effects.

Not all side effects for **INTAZA 100** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **INTAZA 100,** please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, inform your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **INTAZA 100**. 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,
- difficulty breathing,

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- lung, nose and throat infections,
- extreme loss of weight,
- feeling anxious, difficulty sleeping,
- dizziness, burning sensation, numbness,
- blood spots in the skin, blushing, bruising of the skin,
- shortness of breath, throat infection, coughing up blood, blocked nose,
- constipation, loose stomach, feeling sick (nausea), being sick (vomiting), bleeding gums, blood in your stools, blood spots inside your mouth, reddening and swelling on the inside of your mouth, sores on your tongue,
- discolouration of the skin, skin redness, increased sweating, rash, hives,
- muscle weakness, joint pain,
- painful urinating,
- feeling tired, bruising, pain, redness and swelling of at the site of injection, feel tardy.

Less frequent side effects:

- collection of pus under the skin around the anus.

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 "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

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

5. HOW TO STORE INTAZA 100

Store at or below 25 °C.

After reconstitution:

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.

Store all medicines 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 100 contains

- The active substance is azacitidine.
- Each vial contains 100 mg azacitidine.
- The other ingredients are mannitol and water for injection.

What INTAZA 100 looks like and contents of the pack

- INTAZA 100 is a white lyophilized powder or cake
- It is presented in a 30 ml, clear, type 1 glass vial, sealed with a grey bromo-butyl, siliconised rubber stopper and white aluminium flip-off seal.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd.

Building 31, Ground Floor,

Woodlands Office Park,

20 Woodlands Drive, Woodmead,

Johannesburg, 2191

Tel: +27 11 234 5701/2

Email: medinfo@accordhealth.co.za

This leaflet was last revised in

17 November 2020

23 July 2021

Registration number

INTAZA 100: 51/26/0453.452

The package insert is free of typographical and grammatical errors.
Initials: AOO

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