Package leaflet: Information for the patient

REZZAYO 200 mg powder for concentrate for solution for infusion
Rezafungin

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given 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, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What REZZAYO is and what it is used for
2. What you need to know before you are given REZZAYO
3. How REZZAYO is given
4. Possible side effects
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1. What REZZAYO is and what it is used for

What REZZAYO is
REZZAYO contains the active substance rezafungin, which is an antifungal. Rezafungin belongs to a group of medicines called echinocandins.

What REZZAYO is used for
This medicine is given to adults to treat invasive candidiasis, a serious fungal infection in your tissues or organs that is caused by a type of yeast called *Candida*.

How REZZAYO works
This medicine blocks the action of an enzyme (a type of protein) that is needed by fungal cells to make a molecule that strengthens their cell walls. This makes the fungal cells fragile and stops the fungus from growing. This stops the infection from spreading and gives the body's natural defences a chance to remove the infection.

2. What you need to know before you are given REZZAYO

REZZAYO must not be given
- if you are allergic to rezafungin, other echinocandins (such as caspofungin, anidulafungin), or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given REZZAYO.

Effects on the liver
Your doctor may decide to monitor you for liver function more closely if you develop liver problems during your treatment.

Infusion-related reactions
REZZAYO may cause infusion-related reactions, which could include reddening of the skin (flushing), sensation of warmth, nausea (feeling sick) and chest tightness. Your doctor may decide to monitor you during the infusion for signs of an infusion-related reaction. Your doctor may decide to slow down your infusion (drip) if an infusion-related reaction occurs.

Light sensitivity
REZZAYO may increase your risk of phototoxicity (condition in which the skin or eyes become very sensitive to sunlight or other forms of light). During your treatment, and for 7 days after you have been given the last dose of this medicine, you should avoid being out in the sun or using artificial sun tanning lights without protection (like sunscreen).

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

Pregnancy, breast-feeding and fertility
You should not use this medicine unless specifically told by your doctor. If you are pregnant or breast-feeding, or think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine. If you are a woman of childbearing potential, you may be advised by your doctor to use contraception during your therapy with REZZAYO.
The effect of REZZAYO in pregnant or breast-feeding women is not known.

Driving and using machines
This medicine is unlikely to have an effect on driving or using machines.

REZZAYO contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How REZZAYO is given

This medicine will be prepared and given to you by a doctor or a healthcare professional

Recommended dose
Your treatment will start with a 'loading dose' (an initial dose of a medicine which is higher than the maintenance dose) of 400 mg on the first day. This will be followed by a maintenance dose of 200 mg on day 8 of your treatment and once weekly thereafter.

REZZAYO should be given to you once a week, by infusion (a drip) into your vein. This will take at least 1 hour. Your doctor will determine how long the infusion time will be and may increase it to up to 3 hours to avoid infusion-related reactions.

Your doctor will determine how long you need to receive treatment based on your response to the medicine and your condition.

In general, your treatment will continue for at least 14 days after the last day *Candida* was found in your blood.

If symptoms of invasive candidiasis come back, tell your doctor or another healthcare professional immediately.

If you have been given more REZZAYO than you should
You should not receive this medicine more than once a week. If you are concerned that you may have been given too much REZZAYO, tell your doctor or another healthcare professional immediately.

If you miss a dose of REZZAYO
As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However, if you miss an appointment to receive this medicine, contact your doctor or another healthcare professional as soon as possible to schedule a new appointment.

If you stop using REZZAYO
Your doctor will monitor your response and condition to determine when to stop your treatment with this medicine. You should not experience any side effects after this.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects - tell your doctor or another healthcare professional immediately should you experience any of the following side effects:
- reddening of the skin, sensation of warmth, nausea (feeling sick), chest tightness – these may be signs you are having an infusion-related reaction (common – may affect up to 1 in 10 people).

Other side effects

Very common (may affect more than 1 in 10 people)
- low blood potassium level (hypokalaemia)
- diarrhoea
- fever (pyrexia)
- decreased red blood cells (anaemia)

Common (may affect up to 1 in 10 people)
- low blood magnesium level (hypomagnesaemia)
- low blood phosphate level (hypophosphataemia)
- low blood pressure (hypotension)
- wheezing
- vomiting
- feeling sick (nausea)
- stomach (abdominal) pain
- constipation
- redness of the skin (erythema)
- rash
- increased blood levels of alkaline phosphatase, an enzyme (protein) made in the liver, bones, kidney and gut
- increased levels of liver enzymes (including alanine aminotransferase and aspartate aminotransferase)
- increased blood levels of bilirubin, a breakdown product of red blood cells

Uncommon (may affect up to 1 in 100 people)
- high blood phosphate levels (hyperphosphataemia)
- low blood sodium level (hyponatraemia)
- skin or eyes become very sensitive to sunlight or other forms of light (phototoxicity)
- shaking (tremor)
- high blood levels of eosinophils (a type of white blood cell)

Not known (frequency cannot be estimated from the available data)
- Hives (urticaria)

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store REZZAYO

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 and vial label after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Keep the vial in the outer carton in order to protect from light.

Only a trained healthcare professional who has read the complete directions can prepare this medicine for use. Once REZZAYO has been prepared, it should normally be used immediately. However, the reconstituted and diluted infusion solution may be stored up to 24 hours in a refrigerator.

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 protect the environment.

6. Contents of the pack and other information

What REZZAYO contains
- The active substance is rezafungin. Each vial contains 200 mg rezafungin (as acetate).
- The other ingredients are mannitol, histidine, polysorbate 80, hydrochloric acid, sodium hydroxide (see section 2 “REZZAYO contains sodium”).

What REZZAYO looks like and contents of the pack

REZZAYO is a powder for concentrate for solution for infusion in a glass vial with a rubber stopper and an aluminium seal with plastic flip-off cap. It is a white to pale yellow cake or powder.
Each pack contains 1 vial.

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The following information is intended for healthcare professionals only:

REZZAYO should be administered as a single agent via intravenous infusion in sodium chloride 9 mg/mL (0.9 %) solution for injection, sodium chloride 4.5 mg/mL (0.45 %) solution for injection, or 5 % glucose.

INSTRUCTIONS FOR USE IN ADULT PATIENTS

REZZAYO must be reconstituted and diluted prior to administration.

From a microbiological point of view, the reconstituted solution and the diluted solution for infusion should be used immediately. If not used immediately, in-use storage conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C from first opening, unless reconstitution and dilution have taken place in controlled and validated aseptic conditions.

Using aseptic techniques, reconstitute each vial with 9.5 mL water for injections. The concentration of the reconstituted vial will be 20 mg/mL. Do not use sterile sodium chloride 9 mg/mL (0.9 %) solution for injection to reconstitute the vial, only use water for injections.

To minimise foaming, do not shake or mix vigorously. The white to pale yellow powder will dissolve completely. Mix using a gentle swirling motion for up to 5 minutes until the reconstituted solution is a clear, colourless to pale yellow solution. The reconstituted solution should be visually inspected for particulate matter or discolouration. If irregularities are found, do not use the vial.

The vial is for single use only. Therefore, unused reconstituted concentrate must be discarded immediately.

For the 400 mg loading dose, the reconstitution step should be repeated for the additional vial of REZZAYO (refer to dosing table).

The infused total volume should be 250 mL, therefore, the volume of the intravenous infusion bag (or bottle) should be adjusted accordingly, as shown in the dosing table. Aseptically transfer 10 mL from each of the reconstituted vials into an intravenous infusion bag (or bottle) containing either sodium chloride 9 mg/mL (0.9 %) solution for injection, sodium chloride 4.5 mg/mL (0.45 %) solution for injection, or 5 % glucose. The total reconstituted volume to be added to the intravenous bag or bottle is shown in the dosing table. Mix the solution by gentle inversion of the intravenous bag (or bottle). Avoid excessive agitation.

After dilution, the solution is to be discarded if particulate matter or discolouration is identified.

DOSING TABLE - PREPARATION OF THE SOLUTION FOR INFUSION IN ADULTS

Dose (mg)	Number of vials	Volume to be removed from 250 mL intravenous bag/bottle (mL)	Volume of water for injections to be added to each vial (mL)	Total reconstituted volume to add to intravenous bag/bottle (mL)	Total infusion volume (mL)	Final infusion solution concentration (mg/mL)
400	2	20	9.5	20*	250	1.6
200	1	10	9.5	10	250	0.8

* 10 mL from each of two vials totalling 20 mL.