



WHAT YOU SHOULD KNOW ABOUT RUXIENCE®

Important Risk Minimisation Information to assist Healthcare Professionals in:

- Caring for patients receiving Ruxience® therapy
- Communicating that Ruxience® should only be administered as an intravenous infusion

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

ABOUT THIS GUIDE

This guide does not contain all the information about this product. You should always consult the Summary of Product Characteristics (SmPC) before prescribing, preparing or administering Ruxience®. This guide is intended to summarise Important Safety Information about Ruxience® when it is used in oncology indications. This information is intended to assist healthcare professionals in communicating key safety messages and caring for patients receiving Ruxience® therapy.

POSOLOGY AND METHOD OF ADMINISTRATION

Ruxience® should be administered under the close supervision of an experienced healthcare professional, and in an environment where full resuscitation facilities are immediately available (see section 4.4 of the SmPC).

Posology

It is important to check the medicinal product labels to ensure that the appropriate formulation is being given to the patient, as prescribed.

Method of administration

The prepared Ruxience® solution should be administered as an intravenous infusion only through a dedicated line to avoid any administration route errors. It should not be administered as an intravenous push or bolus.

First infusion

The recommended initial rate for infusion is 50 mg/hour; after the first 30 minutes, it can be escalated in 50 mg/hour increments every 30 minutes, to a maximum of 400 mg/hour.

Subsequent infusions

All indications

Subsequent doses of Ruxience® can be infused at an initial rate of 100 mg/hour, and increased by 100 mg/hour increments at 30 minute intervals, to a maximum of 400 mg/hour.



FURTHER INFORMATION

Consult the SmPC before prescribing, preparing, or administering Ruxience[®]. Please contact Pfizer Medical Information at 1800 633 363 if you have any questions.

REFERENCES

1. Ruxience[®] Summary of Product Characteristics. Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium.

Reporting side effects

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.



