

Bendamustine

This Horizons Infosheet contains information on bendamustine (also known as bendamustine hydrochloride, Ribomustin[®], Levact[®] and Treanda[®]), a drug being investigated for the treatment of myeloma.

The Horizons Infosheet series provides information relating to novel drugs that are currently being investigated for the treatment of myeloma. The series also aims to highlight the considerable amount of research currently taking place in the field of myeloma drug development. The drugs described in the Horizons Infosheets may not be

licensed and/or approved for use in myeloma. You may, however, be able to access them as part of a clinical trial.

What is bendamustine?

Bendamustine is a chemotherapy drug. It is not a new drug and has been used to treat certain cancers since the 1970s in Germany.

How does bendamustine work?

Bendamustine works by damaging the DNA within cells. DNA is the genetic material within human cells. Damaging the DNA prevents the repair, replication and multiplication of myeloma cells and results in their death.

How is bendamustine given?

Bendamustine is given as an intravenous infusion (into the vein) over 30 – 60 minutes.

Bendamustine has been shown to be effective as a monotherapy (on its own and not in combination with other drugs), but evidence suggests its effectiveness is increased when used in combination with other drugs such as prednisolone.

Data from the Myeloma UK-funded clinical trial, MUK *one*, demonstrated that a lower dose of bendamustine (60mg/m²) is more effective than a higher dose (100mg/m²) when used in combination with thalidomide and dexamethasone in relapsed myeloma patients.

When given in combination with prednisolone, bendamustine is given on days 1 and 2 of a 28 day cycle. Prednisolone is given orally (by mouth) on days 1, 8, 15 and 22.

What evidence exists to support the use of bendamustine?

Bendamustine has been investigated in combination with several different myeloma treatments and in different patient groups.

Several phase II trials have shown bendamustine to be safe and effective as an initial treatment for newly diagnosed myeloma patients.

There is encouraging evidence that bendamustine is effective in patients with relapsed and/or refractory myeloma when given in combination with other drugs, such as prednisolone, or dexamethasone and lenalidomide (Revlimid®) or bortezomib (Velcade®). However, the optimal dosage, schedule and combination have yet to be determined.

What are the possible side-effects of bendamustine?

The most commonly reported side-effects of bendamustine include: low white blood cell levels (lymphopenia); low platelet levels (thrombocytopenia); low red blood cell levels (anaemia); allergic reactions; fever; nausea and vomiting. You may not lose your hair but it is likely to become thinner.

The side-effects associated with the use of bendamustine will normally resolve when treatment is stopped.

Is bendamustine currently available in any UK clinical trials?

For an up-to-date list of UK clinical trials involving bendamustine, visit the **Myeloma Trial Finder** on **www.myeloma.org.uk**

To be enrolled on a clinical trial, patients have to meet certain conditions known as eligibility criteria. You should speak to your doctor in the first instance if you are interested in taking part in a trial.

UK availability of bendamustine

Before a drug can be widely used, it must first be licensed as a safe and effective treatment.

This is usually done by regulatory authorities at a European level and involves a review of evidence from large-scale clinical trials.

Normally, the licensed drug must then be approved by a UK drug appraisal body before it can be routinely prescribed by NHS doctors. The drug appraisal process differs from licensing – it compares how

effective the newly-licensed drug is to existing drugs already in use on the NHS and decides whether it offers the NHS good value for money. The main body responsible for carrying out drug appraisals in England and Wales is the National Institute for Health and Care Excellence (NICE). NICE recommendations are usually adopted in Northern Ireland. Scotland's drug appraisal body is the Scottish Medicines Consortium (SMC).

Bendamustine has been licensed for use with prednisolone by the European Medicines Agency as an initial treatment option for a specific subgroup of myeloma patients (myeloma patients who are older than 65, who are not suitable candidates for high-dose therapy and stem cell transplantation (HDT-SCT), and who cannot be given either thalidomide or bortezomib). The SMC does not recommend bendamustine to be made available for this group of patients. There are currently no NICE guidelines for bendamustine in myeloma.

Doctors are able to apply to use bendamustine in their patients through a local Individual Funding Request in England and Wales. If approved, this enables doctors to treat individual

patients with bendamustine if they believe it is the best treatment for them.

Future directions

Bendamustine continues to be studied in different patient groups and in different treatment combinations. These trials will provide information about the safest and most effective way to use bendamustine in myeloma.

About this Horizons Infosheet

The information in this Horizons Infosheet is not meant to replace the advice of your medical team. They are the people to ask if you have questions about your individual situation. All Myeloma UK publications are extensively reviewed by patients and healthcare professionals prior to publication.

Other information available from Myeloma UK

Myeloma UK has a range of Essential Guides, Infoguides and Infosheets available covering many areas of myeloma, its treatment and management.

To order your free copies or to talk to one of our Myeloma Information Specialists about any aspect of myeloma, call the **Myeloma Infoline: 0800 980 3332** or **1800 937 773** from Ireland.

The Myeloma Infoline is open from Monday to Friday, 9am to 5pm and is free to phone from anywhere in the UK and Ireland. Information and support about myeloma is also available around the clock at www.myeloma.org.uk

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