



Medicine: arsenic trioxide (brand name: Trisenox®) for acute promyelocytic leukaemia (APL) - resubmission

Teva UK Limited

What is arsenic trioxide used for?

Arsenic trioxide is used to treat acute promyelocytic leukaemia (APL). APL is a rare type of acute myeloid leukaemia, which is a cancer that starts in the bone marrow. In APL, blood producing cells in the bone marrow called promyelocytes don't develop properly and become cancerous. Some of these cancerous cells may have a genetic abnormality called a translocation, which usually leads to the creation of a faulty gene called PML/RAR-alpha.

In this submission, arsenic trioxide was considered for use together with another medicine called all-trans-retinoic acid (ATRA) to treat adults who are newly diagnosed with APL that is low or intermediate risk and where the leukaemia cells have the genetic translocation and/or the faulty PML/RAR-alpha gene. Arsenic trioxide is already in use for the treatment of adults with APL that has stopped responding to treatment (refractory) or has come back after previous treatment (relapsed).

How does arsenic trioxide work?

Arsenic trioxide is a medicine that acts to slow or stop the growth of the cancer cells.

What has SMC said?

SMC has accepted arsenic trioxide for the treatment of adults with APL as described above.



Why has SMC said this?

SMC looks at how well new medicines work compared with current treatments available in Scotland and in relation to how much they will cost to buy and administer (for example, if the medicine has to be given at a clinic or side effects have to be monitored).

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland. When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

To do this SMC consider the following:

- Clinical trial and economic evidence from the company that makes the medicine.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.
- Information from patient groups about the potential impact of the medicine on patients and carers.

After careful consideration, applying extra flexibility because arsenic trioxide is a medicine for a rare condition, SMC was able to accept it as a possible treatment within NHSScotland.

What does SMC's decision mean for me?

If your healthcare professional thinks that arsenic trioxide for use as described above is the right medicine for you, you should be able to have the treatment on the NHS in Scotland. For further information see:

Medicines in Scotland: What's the right treatment for me?

www.healthcareimprovementscotland.org/medicinesbooklet.aspx



More information

The organisations below can provide more information and support for people with APL and their families. SMC is not responsible for the content of any information provided by external organisations.

Bloodwise



<https://bloodwise.org.uk>



0808 2080 888

Leukaemia Care



<https://www.leukaemiacare.org.uk>



0808 8010 444

You can find out more about arsenic trioxide in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.



<http://www.ema.europa.eu>

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