



EMA/467900/2017 Rev. 2

**Update of 4 September 2018**

The shortage affecting Trisenox (arsenic trioxide) has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

31 July 2017

**Shortage of Trisenox (arsenic trioxide)  
Solution for infusion**

<b>Indication</b>	<p>Trisenox is a cancer medicine used to treat a type of blood cancer called acute promyelocytic leukaemia (APL). It is used in adults with either:</p> <ul style="list-style-type: none"><li>• newly diagnosed low or intermediate risk APL, or</li><li>• APL whose disease has not responded to previous treatment with a retinoid and cancer medicines, or when their disease has come back after this type of treatment.</li></ul>
<b>Reason for shortage</b>	<p>Several batches of Trisenox failed standard quality testing at the new manufacturing site. The affected batches were not released and manufacturing was temporarily suspended.</p> <p>Trisenox products currently on the market are not affected by the quality defect, since they have been produced at the previous manufacturing site.</p>
<b>Member States affected<sup>1</sup></b>	<p>By mid/late August 2017, all EU Member States where Trisenox is currently marketed are expected to be out of stock:</p> <p>Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom.</p> <p>However, in most EU countries the shortage can be averted by importing from Australia an arsenic trioxide-containing medicine called Phenasen.</p>

<sup>1</sup> This information may change. For up-to-date information about the status of a medicine shortage in a particular Member State, contact the [national competent authority](#).



## Shortage of Trisenox (arsenic trioxide) Solution for infusion

<b>Information for healthcare professionals</b>	<ul style="list-style-type: none"><li>• A manufacturing issue is affecting the supply of Trisenox and stocks will run out by mid/late August 2017.</li><li>• Most EU countries may be able to import from Australia another arsenic trioxide-containing medicine called Phenasen.</li><li>• Healthcare professionals have been informed in writing about the stock-out and what actions to take.</li><li>• <u>In countries where the arsenic trioxide-containing medicine Phenasen will be imported</u>, prescribers can continue to prescribe arsenic trioxide for APL.</li><li>• Phenasen and Trisenox contain the same active ingredient, arsenic trioxide, in the same total concentration: 10 mg of arsenic trioxide in 10 ml. Whereas Trisenox is available as an ampoule Phenasen is available as a vial.</li><li>• <u>In countries where Phenasen will not be made available</u>, prescribers should not start any newly diagnosed patients with APL on Trisenox and should consider alternative treatment instead.</li><li>• Any remaining stock should only be used for patients with APL who have already started treatment with Trisenox as well as patients with relapsed or refractory APL.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a>.</li></ul>
<b>Information for patients</b>	<ul style="list-style-type: none"><li>• A manufacturing issue is affecting the supply of Trisenox and stocks will run out by mid/late August 2017 across all European countries.</li><li>• Most patients will receive an alternative arsenic trioxide-containing medicine called Phenasen, which is imported from Australia.</li><li>• If Phenasen is not available, to manage remaining stocks of Trisenox efficiently, patients with newly diagnosed APL will not be started on Trisenox. Instead, doctors will consider a suitable alternative.</li><li>• Patients who have already been started on Trisenox may continue their treatment.</li><li>• Trisenox can also continue to be used in patients with APL whose disease has not responded to or has come back after treatment.</li><li>• Patients who have any questions should speak to their doctor or pharmacist.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a>.</li></ul>