30 January 2020
EMA/CHMP/665088/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trepulmix

treprostinil sodium

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trepulmix[2], intended for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH). The applicant for this medicinal product is SciPharm Sarl.

Trepulmix will be available as 1 mg/ml, 2.5 mg/ml, 5 mg/ml and 10 mg/ml solutions for infusion. The active substance of Trepulmix is treprostinil sodium, a prostacyclin analogue which has a direct vasodilatory effect on the pulmonary and systemic arterial circulation and inhibits platelet aggregation.

The benefits with Trepulmix is its ability to provide significant improvement in exercise capacity in patients with CTEPH. The most common side effects are headache, diarrhoea, nausea, jaw pain and infusion site pain.

Trepulmix is a hybrid medicine[3] of Remodulin which has been authorised in the EU since 10 August 2005 and contains the same active substance. Remodulin is licensed for the treatment of pulmonary arterial hypertension.

The full indication is:

"Treatment of adult patients with WHO Functional Class (FC) III or IV and:

- inoperable chronic thromboembolic pulmonary hypertension (CTEPH), or
- persistent or recurrent CTEPH after surgical treatment

to improve exercise capacity."

Treatment with Trepulmix should be started and monitored only by clinicians experienced in the treatment of pulmonary hypertension. Treatment should be started under close medical supervision in a medical facility where intensive care can be provided.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained
[3] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.