



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Arpraziquantel (*arpraziquantel*)

An overview of Arpraziquantel and why it is authorised in the EU

What is Arpraziquantel and what is it used for?

Arpraziquantel is a medicine used to treat children aged 3 months to 6 years with schistosomiasis, a parasitic infection caused by *Schistosoma* worms *S. mansoni* and *S. haematobium*.

This medicine is intended for use outside the EU.

Arpraziquantel contains the active substance arpraziquantel.

How is Arpraziquantel used?

Arrangements for supply of the medicine will be the responsibility of national medicines regulators.

Arpraziquantel tablets are taken by mouth after they have been fully dispersed in water. The number of tablets to be taken depends on body weight and treatment only needs to be taken once.

For more information about using Arpraziquantel, see the package leaflet or contact your healthcare provider.

How does Arpraziquantel work?

Arpraziquantel is the pharmacologically active form of praziquantel (another medicine to treat schistosomiasis). When ingested, the medicine is taken up by the *Schistosoma* worms in a patient's blood vessels. This causes muscle spasms and paralysis in the parasites, which disrupts their attachment to the blood vessel. Arpraziquantel also damages the tegument, a barrier that protects the parasite from the immune system (the body's natural defences). By doing so, the body can destroy the worms.

What benefits of Arpraziquantel have been shown in studies?

In a main study involving 288 children, Arpraziquantel was as effective as praziquantel in removing *S. mansoni* parasites and showed a high cure rate for *S. haematobium* infections. Among 150 children aged 4 to 6 years, 88% of children given Arpraziquantel and 81% of children given praziquantel had no *S. mansoni* eggs in their stool 3 weeks after treatment, indicating that all parasites were killed. In

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addition, among 60 children aged 3 months to 6 years given Arpraziquantel for *S. haematobium* infection, 86% of the children had no *S. haematobium* eggs in their urine 3 weeks after treatment.

What are the risks associated with Arpraziquantel?

For the full list of side effects and restrictions with Arpraziquantel, see the package leaflet. The most common side effects with Arpraziquantel (which may affect up to 1 in 10 people) include abdominal (belly) pain, diarrhoea, vomiting and somnolence (sleepiness).

Arpraziquantel must not be used in patients who have or are suspected to have cysticercosis (a parasitic tapeworm infection) or acute schistosomiasis (the stage of infection at which *Schistosoma* larvae migrate in the body) and it must not be used together with certain medicines that reduce its effectiveness (so-called cytochrome P450 inducers).

Why did Arpraziquantel receive a positive opinion?

The European Medicines Agency decided that Arpraziquantel's benefits are greater than its risks. A main study has shown that the effectiveness of Arpraziquantel is comparable to that of praziquantel for treating schistosomiasis caused by *S. mansoni* or *S. haematobium*. Arpraziquantel tablets are easier to dose in young children aged 3 months to 6 years and the active substance has a more acceptable taste. The side effects of the medicine are considered mild to moderate.

What measures are being taken to ensure the safe and effective use of Arpraziquantel?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Arpraziquantel have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Arpraziquantel are continuously monitored. Suspected side effects reported with Arpraziquantel are carefully evaluated and any necessary action taken to protect patients.

Other information about Arpraziquantel

The European Medicines Agency gave a positive opinion for Arpraziquantel on 14 December 2023.

The Agency assessed Arpraziquantel as part of its cooperation with the World Health Organization, whereby the Agency evaluates medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

Further information on Arpraziquantel can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/arpraziquantel

This overview was last updated in 01-2024.