

RECOMMENDED CHANGES TO THE PRODUCT INFORMATION

The following changes to the product information of medicinal products containing the active substance biperiden are recommended:

4.8 Undesirable effects

The following frequencies are used as the basis in the evaluation of side-effects:

Very common	(> 1/10)
Common	(> 1/100 to <1/10)
Uncommon	(≥ 1/1,000 to < 1/100)
Rare	(≥ 1/10,000 to < 1/1,000)
Very rare	(<1/10,000)
Not known	(cannot be estimated from the available data)

Side-effects may occur particularly at the beginning of treatment and if the dosage is increased too quickly. Due to the unknown number of users, the percentage frequency of spontaneously recorded side-effects cannot be determined exactly.

Infections and infestations

Not known: Parotitis.

Immune system disorders

Very rare: Hypersensitivity.

Psychiatric disorders

Rare: In higher doses excitement, agitation, fear, confusion, delirious syndromes, hallucinations, sleeplessness. Central excitation effects are frequently seen in patients with symptoms of a cerebral deficiency and can necessitate a decrease in the dosage. There have been reports of temporarily reduced REM sleep (sleeping phase with rapid eye movements), characterised by an increase in the time needed to reach this stage and a percentage decrease in the length of this phase in the total sleep.

Very rare: Nervousness, euphoria.

Nervous system disorders

Rare: Fatigue, dizziness and disturbance of memory.

Very rare: Headache, dyskinesia, ataxia and speaking disorder, increased disposition to cerebral seizures and convulsions.

Eye disorders

Very rare: Disturbance of accommodation, mydriasis, and photosensitivity. Closed-angle glaucoma might occur (controlling of intraocular pressure).

Cardiac disorders

Rare: Tachycardia

Very rare: Bradycardia. A fall in blood pressure may occur following parenteral administration.

Gastrointestinal disorders

Rare: Dryness of mouth, nausea, gastric disorder.

Very rare: Constipation

Skin and subcutaneous tissue disorders

Very rare: Reduced perspiration, allergic rash.

Musculoskeletal and connective tissue disorders

Rare: Muscle twitching.

Renal and urinary disorders

Very rare: Voiding disorders, especially in patients with prostate adenoma (dose reduction), more seldom: urinary retention.

General disorders and administration site conditions

Rare: Drowsiness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.