

Core Safety Profile

CRH (corticotropin (human) trifluoroacetate)

4.3 Contraindications

Hypersensitivity to corticotropin (human) trifluoroacetate or to any of the excipients.

4.4 Special warnings and precautions for use

Testing with corticotropin has to be done and monitored by a specialist physician experienced in pituitary function exploration. Because of intravenous route and type of product (peptidic), hypersensitivity reactions may occur. Appropriate medical support measures should be readily available when this product is administered.

CRH is not recommended for use in children due to insufficient data on safety and efficacy.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant administration of the following should be avoided:

- Drugs that inhibit the action of CRH such as corticosteroids, antihistamines, antiserotonergic substances and oxytocin.
- Drugs that increase the potency of CRH such as vasopressin and its analogues.

4.6 Pregnancy and lactation

There are no adequate data from the use of CRH in pregnant women.

Animal studies are insufficient with respect to effects on pregnancy. The potential risk for humans is unknown.

There is insufficient information on the excretion of corticotropin in human or animal breast milk. The potential for adverse effects in the nursing infant from exposure to the drug is unknown. Corticotropin is not recommended in women who are pregnant or breastfeed their infants.

Administration during third trimester of pregnancy is not indicated due to the difficulty of results interpretation during pregnancy.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Due to the short duration of action of corticotropin the influence on the ability to drive and use machines is expected to be negligible.

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4.8 Undesirable effects

MedDRA Organ Class	Very common (>10%)	Common (1-10%)	Uncommon (0.1-1%)	Rare (0.01-0.1%)	Very rare (<0.01%)
Immune system disorders			Hypersensitivity		Anaphylactic reactions
Nervous system disorders		Transient disturbance of sensation of smell and taste			
General disorders and administration site conditions		Transient sensation of warmth			

4.9 Overdose

Higher dosages may lead to episodic blood pressure decrease with accelerated heart action and increased prolactin release.

In case of overdose, the reported undesirable effects may occur (see section 4.8). Since corticotropin is eliminated rapidly from the body, no measures in case of overdose are necessary.