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Javna agencija Republike Slovenije  
za zdravila in medicinske pripomočke  
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VSEM IMETNIKOM DOVOLJENJ ZA PROMET Z  
ZDRAVILI, KI VSEBUJEJO SEME JAJČASTEGA  
TRPOTCA

**Zahteva za predložitev spremembe tipa IB – dopolnitev povzetka glavnih značilnosti zdravila in navodila za uporabo za zdravila, ki vsebujejo seme jajčastega trpotca**

Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) pri Evropski agenciji za zdravila EMA je v oktobru 2011 pregledala podatke o pojavu preobčutljivosti, do katere je prišlo pri pripravi peroralne suspenzije zdravila iz praška. Na osnovi ocene podatkov je zaključila, da je treba informacije o zdravilih, ki vsebujejo seme jajčastega trpotca (*Plantaginis ovatae semen*) in so v obliki praškov, ustrezno dopolniti.

Imetnike dovoljenj za promet z zadevnimi zdravili, ki vloge za spremembo dovoljenja za promet še niso vložili, prosimo, da Javni agenciji RS za zdravila in medicinske pripomočke v skladu s Pravilnikom o dovoljenju za promet z zdravilom za uporabo v humani medicini (Uradni list RS, št. 109/2010) predložijo spremembo tipa IB. Vlogo za zadevna zdravila, ki so pridobila dovoljenje za promet po nacionalnem postopku, imetniki dovoljenj za promet predložijo najkasneje v 30 dneh ob objave obvestila, za zdravila, ki so pridobila dovoljenje za promet po mednarodnih postopkih, pa v skladu s časovnico referenčne države članice (RMS). Dodatne informacije in podporna dokumentacija v vlogi niso potrebne.

V nadaljevanju vam podajamo odobreno originalno besedilo spremembe, objavljeno je tudi na spletni strani Vodij agencij za zdravila <http://www.hma.eu/222.html>.

S spoštovanjem,

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## SUMMARY OF PRODUCT CHARACTERISTICS

### 4.2 Posology and method of administration (...)

When preparing the product for administration, it is important to try to avoid inhaling any of the powder in order to minimize the risk of sensitization to the active ingredient.

### 4.3. Contraindications

Addition of a cross reference to section 4.4: "(see 4.4 Special warnings and precautions for use)", following the current statement on the contraindication in patients with known hypersensitivity to the product.

### 4.4. Special warnings and precautions for use (...)

#### Warning on hypersensitivity reactions

In individuals with continued occupational contact to powder of *Plantago ovata* seeds (i.e. healthcare workers, caregivers) allergic sensitization may occur due to inhalation, this more frequent in atopic individuals. This sensitization usually leads to hypersensitivity reactions which could be serious (see 4.8 Undesirable effects).

It is recommended to assess clinically the possible sensitization of individuals at risk and, if justified, to perform specific diagnostic tests.

In case of proven sensitization leading to hypersensitivity reactions, exposure to the product should be stopped immediately and avoided in the future (see 4.3 Contraindications)."

### 4.8. Undesirable effects (...)

"Ispaghula/psyllium husk contains potent allergens. The exposure to these allergens is possible through oral administration, contact with the skin and, in the case of powder formulations, also by inhalation.

As a consequence to this allergic potential, individuals exposed to the product can develop hypersensitivity reactions such as rhinitis, conjunctivitis, bronchospasm and in some cases, anaphylaxia. Cutaneous symptoms as exanthema and/or pruritus have also been reported. Special attention should be given to individuals manipulating the powder formulations routinely (see 4.4 Special warnings and precautions for use)."

### 6.6. See 4.2

## PACKAGE LEAFLET

### 2. What you need to know before you use <X>

Do not use <Herbal medicinal product>:

if you are allergic to plantago ovata seeds or any of the other ingredients of this medicine (see in this section "Warnings and precautions" below)

(...)

Warnings and precautions:

Talk to your doctor or pharmacist before taking < Herbal medicinal product >:

if you are a healthcare worker or care giver who has been preparing for administration products with powder of plantago ovata seeds to patients for a long time You might have become allergic to these products due to continued inhalation of the powder. In case of symptoms (listed in section 4) are confirmed as allergic, do not use the product (see in this section, "Do not use")

### 3. How to use < Herbal medicinal product >

(...)

(At the end of the paragraph describing the method of administration)

When preparing the product for administration it is important to try to avoid inhaling the powder.

### 4. Possible side effects

(...)

(At the end of the paragraph describing the possibility of allergic reactions)

Plantago ovata seeds contain substances which may lead to allergic reactions after use of the product by the oral route, contact with the skin or, in case of powder formulations, also by inhalation.

The allergic symptoms may include running nose, redness of the eye, difficulty in breathing, skin reactions, itching, and in some cases anaphylaxis (a sudden, generalised allergic reaction that may lead to life-threatening shock). Individuals manipulating the powder formulations routinely are more prone to these reactions (see section 2).