12.05.2020

VERORAB (RABIES, INACTIVATED, WHOLE VIRUS 2.5 IU) powder and solvent for suspension for injection\ ורוראב אבקה וסולבנט לתרחיף להזרקה

רופא/ה נכבד/ה ,רוקח/ת נכבד/ה,

חברת מדיצ'י מדיקל בע"מ מודיעה על עדכון העלון לרופא. בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה החמרה. עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (שינוי שהינו הוספה מסומן בצבע תכלת- update ,מחיקה מסומנת בקו אמצעי אדום- והחמרה ברקע צהוב Worsening.

ההתוויה הרשומה לתכשיר בישראל:

Prevention of rabies in children and adults.

It can be used before and after exposure, as a primary vaccination or as a booster dose.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

[….]

4.4. Special warnings and precautions for use

Special warnings

[….]
As with all vaccines, VERORAB may not protect 100% of people vaccinated.

Use with caution in people with known allergies to polymyxin B, to streptomycin, to neomycin (present as traces in the vaccine) or to any antibiotic of the same group.

Precautions for use

Serological tests (assay of neutralising antibodies using the RFFIT - Rapid Fluorescent Focus Inhibition Test - method) should be performed regularly (see Table 1).

When the vaccine is administered to subjects with a known immunodeficiency due to an immunosuppressive illness or a concomitant immunosuppressive treatment (such as corticosteroids), a serological test should be performed 2 to 4 weeks after vaccination (see section 4.2).

Do not inject via the intravascular route: make sure the needle does not penetrate a blood vessel.

As with all injectable vaccines, appropriate medical treatment and supervision must be readily available in case of a rare anaphylactic reaction after vaccine administration, particularly in case of post-exposure in subjects with a known hypersensitivity to polymyxin B, to streptomycin, to neomycin or to any antibiotic of the same group.

As with all injectable vaccines, VERORAB should be administered with caution in subjects with thrombocytopenia or coagulation disorders as intramuscular injection may induce bleeding in these subjects.

The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance and paraesthesia. It is important that procedures are in place to avoid injury from faints.

[….]

4.8. Undesirable effects

Undesirable effects were reported during clinical studies and after commercial use.

Undesirable effects are ranked in terms of frequency:
- very common: ≥ 1/10
- common: ≥ 1/100 and < 1/10
- uncommon: ≥ 1/1 000 and < 1/100
- rare: ≥ 1/10 000 and < 1/1 000
- very rare: < 1/10 000 including isolated cases.

Experience from clinical trials

Blood and lymphatic system disorders

Very common: adenopathy/lymphadenopathy.

Immune system disorders

Common: cutaneous allergic reactions such as rash, pruritus, oedema.
Uncommon: urticaria, angioedema, dyspnoea.

Nervous system disorders
Common: headache, dizziness, somnolence.

Gastrointestinal disorders

Common: abdominal pain, nausea.
Uncommon: diarrhoea.

Musculoskeletal and connective tissue disorders

Very common: myalgia.
Common: arthralgia, shivering.

General disorders and administration site conditions

Very common: Injection-site pain, fever, malaise.
Common: injection-site erythema, injection-site pruritus, injection-site haematoma, injection-site induration, asthenia, influenza-like syndrome.
Uncommon: injection-site swelling.

Experience after commercial use

In addition to the list above, the following undesirable effects were reported. Their exact incidence cannot be calculated as they were spontaneously reported. However, given the number of doses sold, the occurrence of these undesirable effects is very rare (<1/10 000).

Immune system disorders
Anaphylactic reactions, serum sickness-like reactions.

Nervous system disorders
Encephalopathy, convulsions.

Ear and labyrinth disorders
Sudden hearing loss.*
*Which may persist.

Respiratory, thoracic and mediastinal disorders
Apnoea in very premature infants (born ≤ 28 weeks of gestation) (see section 4.4).

Gastrointestinal disorders
Vomiting.

6. PHARMACEUTICAL PARTICULARS
[….]

6.2. Incompatibilities
The rabies immunoglobulins and the rabies vaccine must never be combined in the same syringe or injected at the same injection site.
This medicinal product must not be mixed with other medicinal products or other vaccines.

6.4. Special precautions for storage

Store in a refrigerator (2°C-8°C). Do not freeze.
Store in the original outer package, protected from light.
[….]

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#!/byDrug

וניתן לקבלו מודפס על ידי פניה לבעל הרישום מדיצ'י מדיקל בע"מ, רחוב המחשב 3 נתניה טלפון 09-7446170

בברכה,

האלה ביאדסה

רוקחת ממונה