TETAVAX

ADSORBED TETANUS VACCINE
Suspension for injection in single dose

Read all of this leaflet carefully before you start using this medicinal product. It contains important information for your treatment.

- If you have any further questions, ask your doctor or pharmacist.
- Keep this leaflet. You may need to read it again.
- If you need more information or advice, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. WHAT TETAVAX IS AND WHAT IT IS USED FOR
This vaccine is an anti-infectious medicinal product indicated in the prevention of tetanus.

PERSONS INFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS (HIV):
According to W.H.O. recommendations, any person infected with HIV, symptomatic or asymptomatic, should be immunized with the TETAVAX vaccine according to the usual schedule.

2. BEFORE YOU USE TETAVAX
Do not use TETAVAX in the following cases:
- If you are allergic to any of the vaccine components.
- If you experienced allergic reactions or neurological disorder after a previous vaccine injection.
- If you have fever or an acute disease or chronic progressive illness, vaccination should be postponed.

IF YOU HAVE DOUBTS, IT IS IMPORTANT THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with TETAVAX:
Inform your doctor:
- If you suffer from immunodeficiency or if you follow an immunosuppressive treatment.
- If you are allergic or if you have already experienced an abnormal reaction during a previous vaccine administration.
- If you received a tetanus vaccine in the previous five years.
- If you presented with Guillain-Barre syndrome (abnormal sensitivity, paralysis) or brachial neuritis (paralysis, diffuse pain in arm and shoulder) following receipt of prior tetanus
toxoid containing vaccine (vaccine against tetanus), the decision to give any further vaccine containing tetanus toxoid should be carefully evaluated by your doctor.

**Using other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Pregnancy and lactation**

**Pregnancy**
If needed, the vaccine may be administered during pregnancy.
Ask your doctor or pharmacist for advice before taking any medicine.

**Lactation**
Ask your doctor or pharmacist for advice before taking any medicine.

**Important information about some of the ingredients of TETAVAX:** Potassium

### 3. HOW TO USE TETAVAX

#### Dosage

**Post-tetanus exposure prophylactic vaccination**
The recommended schedule below should be complied with:

<table>
<thead>
<tr>
<th>TYPE OF WOUND</th>
<th>PATIENT NOT IMMUNISED OR PARTIALLY IMMUNISED</th>
<th>PATIENT COMPLETELY IMMUNISED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time since last booster dose</td>
<td>5 to 10 years</td>
</tr>
<tr>
<td><strong>Minor - clean</strong></td>
<td>Begin or complete vaccination:</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Tetanus toxoid, 1 dose of 0.5 ml</td>
<td></td>
</tr>
<tr>
<td><strong>Major - clean or tetanus - prone</strong></td>
<td>In one arm:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Human tetanus immunoglobulin, 250 I.U.*</td>
<td>Tetanus toxoid: 1 dose of 0.5 ml</td>
</tr>
<tr>
<td></td>
<td>In the other arm:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tetanus toxoid**: 1 dose of 0.5 ml</td>
<td></td>
</tr>
<tr>
<td><strong>Tetanus-prone</strong></td>
<td>In one arm:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Human tetanus immunoglobulin, 500 I.U.*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>In the other arm:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tetanus toxoid**: 1 dose of 0.5 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antibiotic therapy</td>
<td></td>
</tr>
</tbody>
</table>

* = In the other arm: Human tetanus immunoglobulin, 1000 I.U.
* Use different syringes, needles and injection sites.
** Complete the vaccination according to the vaccination schedule.

**Neonatal tetanus prophylaxis**
Women of childbearing age or pregnant women that have not yet been immunised must have 2 successive injections at least 4 weeks apart; the first one shall preferably be administered 90 days or more before birth.

*Primary immunisation*: 2 successive injections one or two months apart followed by a booster 6 to 12 months after the second injection.

*Booster injection*: 1 dose 10 years after primary immunisation and every 10 years thereafter.

**Route of administration**
Shake before injection until a homogeneous suspension is obtained.
It is preferable to administer the vaccine by the intramuscular route in order to minimize local reactions. The deep subcutaneous route may also be used. The intradermal route should not be used.

4. **POSSIBLE SIDE EFFECTS**
Like all medicines, TETAVAX can cause side effects, although not everybody gets them. The reported side effects are as follows:
- Swelling of lymph nodes.
- Allergic or hypersensitivity reactions: urticaria, swelling (oedema).
- Skin reaction: itching (pruritus), skin redness (erythema).
- Headache, malaise.
- Hypotension.
- Muscle and joint pain.
- Injection site reactions such as pain, rash, induration or oedema within 48 hours and persisting 1 to 2 days. These reactions may sometimes be accompanied with nodules and, exceptionally, with uninfected abscesses.
- Transient fever, malaise.

The possible side effect (i.e. those which were not directly reported with TETAVAX but with other vaccines containing or several constituents of TETAVAX) are as follows:
- Guillain-Barre syndrome (abnormal sensitivity, paralysis) and brachial neuropathy (paralysis, diffuse pain in arm and shoulder) following receipt of prior tetanus toxoid containing vaccine.

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.
If any other side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE TETAVAX**
Keep out of the reach and sight of children.
Do not use TETAVAX after the expiry date which is stated on the label, carton.
Store between +2°C to +8°C (in a refrigerator). Do not freeze.
After opening: the product should be used immediately.
Medicines should not be disposed of via wastewater or household waste.
Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What TETAVAX contains
The active substance is:
One dose (0.5 ml) contains:
Tetanus toxoid .................................................≥ 40 I.U.
Adsorbed on hydrated aluminum hydroxide ..........0.6 mg Al

The other ingredients are:
A buffer solution containing sodium chloride, disodium dihydrate phosphate, monopotassium phosphate and water for injections.

What TETAVAX looks like and contents of the pack
This medicinal product is a suspension for injection in single doses. Box of 20 ampoules or box of 1 prefilled syringe.

This leaflet was last approved in 12/2010.