

## PACKAGE LEAFLET: INFORMATION FOR USE

### Luivac tablets

#### Composition

##### Pharmaceutically active ingredients:

1 tablet contains:

*Lysate from Staphylococcus aureus, Streptococcus mitis, Streptococcus pyogenes, Streptococcus pneumoniae, Klebsiella pneumoniae, Branhamella catarrhalis and Haemophilus influenza influenza* (of at least  $1 \times 10^9$  germs each).

##### Other ingredients:

Mannitol, Microcrystalline cellulose, Carboxymethyl starch sodium (Type A), Magnesium stearate, Highly disperse silicon dioxide.

#### Presentation and content

Luivac is available in packages containing 14 and 28 tablets.

#### Manufacturer and pharmaceutical entrepreneur

DAIICHI SANKYO EUROPE GmbH  
Zielstattstrasse 48  
D-81379 Munich  
Germany

#### Indications

Recurrent respiratory tract infections such as bronchitis, rhinitis, sinusitis, otitis, pharyngitis and laryngitis.

#### Contra-indications

##### When should Luivac not be used?

Do not take Luivac,

- if you are known to be hypersensitive (allergic) to one of the constituents of Luivac.
- if you suffer from acute gastro-intestinal inflammation.
- if you suffer from an autoimmune disease.
- if you are pregnant.

##### What should you consider during pregnancy and lactation?

As a precaution, Luivac should not be taken during pregnancy as sufficient experience in regard to its use in pregnant women is not available. If you become pregnant during the treatment with Luivac, there is no reason for concern, however. Simply stop taking the tablets. You may take Luivac during lactation period.

#### Interactions with other drugs

##### Which other drugs are influenced in their efficacy by Luivac?

Please inform your doctor or pharmacist, if you are taking or have been taking until recently other medicine, including medicine obtained without a prescription.

To date no intolerances between Luivac and other medicine have been observed.

However, if you are simultaneously treated with medicine that suppresses the body's immune defence (immunosuppressive drugs), a decrease in the effect of Luivac is possible. Please note that this information may also apply, if you are currently no longer using the above medicine but have taken it until recently.

#### Dosage, mode and duration of treatment

*The following information applies unless your physician has prescribed a different use of Luivac. Please follow the directions for use because, otherwise, Luivac may not have the desired effect.*

##### How often should you take Luivac and how many should you take?

If the doctor has not prescribed anything else, the usual dose is:

	Single dose	Maximum daily dose
Adults	1 tablet	1 tablet
Children from the age of 2 years	1 tablet	1 tablet

An age dependent adjustment of dosage is not required.

Please start the treatment by taking one tablet from the pocket bearing the name of the respective weekday (e.g. "Mo" for Monday) and then take one tablet daily from the next pocket in the direction of the arrow.

##### How and when should you take Luivac?

Take Luivac in the morning on an empty stomach and swallow the tablet unchewed with some water. Luivac should not be taken with food and liquids other than water. The tablet can be crushed before use in small children.

##### For how long should you take Luivac?

Luivac tablets should be taken at least for 4 weeks (28 days). After a treatment-free period of 4 weeks, a second intake period of 4 weeks follows. Further treatment periods may follow after 28-day intervals.

Your physician will decide the duration of treatment for your specific case.

If a respiratory tract infection occurs despite the treatment with Luivac, this does not mean that Luivac is not effective for you. The development of body's own defences takes some time. Therefore you should continue taking the tablets as directed. You should ask your doctor whether you should take additional medicine. If your doctor prescribes antibiotics, you may take Luivac simultaneously with the antibiotics. However, Luivac cannot replace a treatment with antibiotics!

#### Overdosage and other mistakes in use

##### What can you do if you have taken too many Luivac (accidental overdosage)?

After the use of larger numbers of Luivac tablets, gastro-intestinal complaints and diarrhoea may occur. Serious side-effects are not to be expected. However, as a precaution, you should consult a doctor, if complaints occur after the intake of larger

numbers of Luivac tablets.

**What should you consider if you have forgotten to take Luivac?**

If you have forgotten to take a Luivac tablet in the morning, you may take it in the course of the day. In this case you should do this half an hour before a meal.

If you have completely forgotten the intake on one or more days, you should simply take one tablet on each of the following days until all 28 tablets have been taken.

If you have forgotten to take your tablet one day, do not take two tablets the next day. Remember to continue the treatment by taking the next tablet from the pocket with the name of the correct weekday from the calendar pack, i.e. skip the pockets containing the tablets for the days missed. Only after you have reached the end of the blister, you should take these tablets.

If you have forgotten to take your tablets of several days, please inform your doctor as the full efficacy of Luivac may no longer be assured in this case.

If you have mistakenly taken two instead of one tablet on one day, simply do not take a tablet the next day. On the following day you can then take your next tablet from the pocket with the name of the correct weekday.

**What should you consider if you interrupt the treatment or discontinue it prematurely?**

The development of body's own defences requires a certain period of time. If you interrupt the treatment or discontinue it early, Luivac cannot become fully effective.

**Side effects**

**Which side effects may occur during a treatment with Luivac?**

Luivac is usually well tolerated. Like all medicines, Luivac can cause side effects, although not everybody gets them. For the assessment of the side effects, the following frequency rating was used:

Very common	in more than 1 in 10
Uncommon	in less than 1 in 10, but more than 1 in 100 patients treated
Rare	in less than 1 in 1,000, but more than 1 in 10,000 patients treated
Very rare	in less than 1 in 10,000 patients treated, including isolated reports

Uncommon:

Gastro-intestinal complaints, usually of slight nature.

Skin reactions (rash).

Very rare:

Painful joints (arthralgia).

Reduced number of blood platelets (thrombocytopenia).

*If you notice adverse reactions that have not been indicated in this package insert, please inform your physician or pharmacist.*

**Which measures are to be taken in the case of side effects?**

If side effects occur your doctor will decide which measures have to be taken. He will also decide whether you should continue taking Luivac.

**Notes and information on the shelf-life of the drug**

Do not use Luivac after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

**How should you store Luivac?**

Keep out of the reach and sight of children.

Store below 30 °C.

**Information dated:** July 2014

<b>THIS IS A MEDICAMENT</b>
<ul style="list-style-type: none"><li>– A drug is a product which acts on your health and its consumption could be dangerous when you do not follow the instructions.</li><li>– Follow strictly the doctor's prescriptions, the method of use and the instructions of the pharmacist who sold the medicament.</li><li>– The doctor and the pharmacist know the medicine, its benefits and risks.</li><li>– Do not by yourself interrupt the period of treatment prescribed for you.</li><li>– Do not repeat the same prescription without consulting your doctor.</li></ul>
<b>KEEP ALL MEDICAMENTS OUT OF REACH OF CHILDREN</b>

Council of Arab Health Ministers and Union of Arab Pharmacists.