Ventavis 10 microgram/ml nebuliser solution

Last Updated on eMC 14-Dec-2016 View document | Bayer plc Contact details

Versions

When a pharmaceutical company changes an SPC or PIL, a new version is published on the eMC. For each version, we show the dates it was published on the eMC and the reasons for change.

Updated on 14-Dec-2016 and displayed until Current

Reasons for adding or updating:

- Change to section 6.3 - Shelf life

Date of revision of text on the SPC: 13-Oct-2016

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

An error was noted in section 6.3 “Shelf life” which currently states:

Ventavis 20 microgram/ml nebuliser solution

2 years.

Ventavis 20 microgram/ml nebuliser solution

5 years.

This has now been corrected to state:

Ventavis 10 microgram/ml nebuliser solution

2 years.

Ventavis 20 microgram/ml nebuliser solution

5 years.

Updated on 21-Nov-2016 and displayed until 14-Dec-2016

Reasons for adding or updating:

- Change to section 1 - Name of the medicinal product
- Change to section 2 - Qualitative and quantitative composition
- Change to section 3 - Pharmaceutical form
- Change to section 4.2 - Posology and method of administration

- Change to section 4.5 - Interaction with other medicinal products and other forms of interaction
- Change to section 4.8 - Undesirable effects - how to report a side effect
- Change to section 5.1 - Pharmacodynamic properties
- Change to section 5.2 - Pharmacokinetic properties
- Change to section 5.3 - Preclinical safety data
- Change to section 6.3 - Shelf life
- Change to section 6.5 - Nature and contents of container
- Change to section 6.6 - Special precautions for disposal and other handling
- Change to section 8 - Marketing authorisation number(s)

Date of revision of text on the SPC: 13-Oct-2016

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The key changes are:

- To add information on the Breelib Inhaler.
- New combined SmPC for 10 & 20 microgram/ml nebulizer solution.

Updated on 11-Dec-2014 and displayed until 21-Nov-2016

Reasons for adding or updating:

- Change to section 6.5 - Nature and contents of container
- Change to section 8 - Marketing authorisation number(s)
- Change to section 10 - Date of revision of the text

Date of revision of text on the SPC: 07-Nov-2014

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The key changes are:

- Section 6.5: 1 ml nebuliser solution – packages containing 30, 42 or 168 ampoules
- Section 8: new MA numbers added for the new pack size.

Updated on 05-Aug-2014 and displayed until 11-Dec-2014

Reasons for adding or updating:

- Change to section 2 - Qualitative and quantitative composition
- Change to section 4.4 - Special warnings and precautions for use
- Change to section 5.2 - Pharmacokinetic properties
- Change to section 10 - Date of revision of the text

Date of revision of text on the SPC: 18-Jul-2014

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The key changes are:

- Clearer statement of ethanol content in **section 2**
- In **section 4.4** a heading has been added for Pulmonary veno-occlusive disease and an additional statement "Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease."
The remainder of the paragraph (Should signs of pulmonary oedema occur…….) has been included in the previous version of the SmPC but has now been relocated under this PVOD heading. The end of the paragraph states that Ventavis should be discontinued (rather than stopped as previous version).
- In **section 5.2** under the heading "Age and gender" there is now a statement that PK data are not available for the elderly.

Updated on 09-Jan-2014 and displayed until 05-Aug-2014

Reasons for adding or updating:

- Change to section 4.2 - Posology and method of administration
- Change to section 4.4 - Special warnings and precautions for use
- Change to section 4.5 - Interaction with other medicinal products and other forms of interaction
- Change to section 4.8 - Undesirable effects
- Change to section 5.1 - Pharmacodynamic properties
- Change to section 5.2 - Pharmacokinetic properties
- Change to section 6.1 - List of excipients

Date of revision of text on the SPC: 21-Nov-2013

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

Updates to Sections 4.8 of the SmPC:

- Addition of 'Cardiac disorders' to the ADR table including tachycardia and palpitations as common events
- Addition of 'General disorders and administration site conditions' to the ADR table including peripheral oedema as a very common event
- Deletion of nasal congestion from 'Respiratory, thoracic and mediastinal disorders (frequency not known).

In addition the following sentence was added to the 'bleeding events' subsection underneath the ADR table (below the heading 'Description of selected adverse reactions'):

'The risk of bleeding may be increased in patients when potential inhibitors of platelet aggregation or anticoagulants are given concomitantly (see section 4.5).'

The standard warning on reporting of suspected adverse reactions has also now been added to this section.

Other changes are editorial and have been made to sections 4.2, 4.4, 5.1, 5.2 and 6.1.

Updated on 10-Sep-2013 and displayed until 09-Jan-2014

Reasons for adding or updating:

- Change to section 2 - Qualitative and quantitative composition
- Change to section 4.1 - Therapeutic indications
- Change to section 4.3 - Contraindications
- Change to section 4.4 - Special warnings and precautions for use
- Change to section 4.5 - Interaction with other medicinal products and other forms of interaction
- Change to section 4.6 - Fertility, pregnancy and lactation
- Change to section 4.7 - Effects on ability to drive and use machines
- Change to section 4.8 - Undesirable effects
- Change to section 4.9 - Overdose
- Change to section 5.1 - Pharmacodynamic properties
- Change to section 5.2 - Pharmacokinetic properties
- Change to section 10 - Date of revision of the text

Date of revision of text on the SPC: 26-Aug-2013

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The key changes are:

- Approval of Renewal of the licence: updates to sections: 2 (Qualitative and Quantitative Composition), 4.1 (Therapeutic Indications), 4.2 (Posology and method of administration), 4.3 (Contraindications), 4.4 (Special warnings and precautions for use), 4.5 (Interaction with other medicinal products and other forms of interaction), 4.6 (Fertility, pregnancy and lactation), 4.7 (Effects on ability to drive and use machines), 4.8 (Undesirable effects), 4.9 (Overdose), 5.1 (Pharmacodynamic properties), 5.2 (Pharmacokinetic properties), 10 (Date of revision of the text).

Updated on 25-Mar-2013 and displayed until 10-Sep-2013

Reasons for adding or updating:

- Change to section 4.3 - Contraindications
- Change to section 4.6 - Fertility, pregnancy and lactation
- Change to section 4.8 - Undesirable effects
- Change to section 10 - Date of revision of the text

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The key changes are:

- Section 4.3 where 'pregnancy & lactation' have been removed as a CI
- Section 4.6 where a section on 'fertility' has been added.
- Section 4.8 a sentence on serious ARs has been added in the introduction and 'thrombocytopenia' has been added to the ADR table.
- Other editorial type changes have also been made to other sections of the SmPC.

Updated on 31-Aug-2011 and displayed until 25-Mar-2013

Reasons for adding or updating:

- Change to section 7 - Marketing Authorisation Holder
- Change to section 10 date of revision of the text

Date of revision of text on the SPC: 01-Jul-2011

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The key changes are:

The name of the Marketing Authorisation Holder and manufacturers have changed from Bayer Schering Pharma AG to Bayer Pharma AG.

Updated on 08-Mar-2011 and displayed until 31-Aug-2011

Reasons for adding or updating:

- Change to section 4.2 - Posology and method of administration
- Change to section 4.4 - Special warnings and precautions for Use
- Change to section 4.5 - Interaction with other medicinal products and other forms of interaction
- Change to section 4.8 - Undesirable Effects
- Change to section 4.9 - Overdose
- Change to section 5.1 - Pharmacodynamic Properties
- Change to section 5.2 - Pharmacokinetic Properties
- Change to section 5.3 - Preclinical Safety Data

Date of revision of text on the SPC: 21-Feb-2011

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The SmPC has been updated as follows:

minor editorial changes have been made throughout

4.2 amended to include concomitant therapy and additional info on renally impaired patients.

4.4 amended to include additional info on blood pressure.

4.5 amended to include hypotension.

4.8 all side effects are now incorporated into the MedDRA table - some frequencies have changed.

4.9 symptoms expanded.

5.1 STEP trial added.

5.2 & 5.3 minor amendments.

Updated on 24-Jan-2011 and displayed until 08-Mar-2011

Reasons for adding or updating:

- Change to section 4.2 - Posology and method of administration
- Change to section 4.6 - Pregnancy and Lactation
- Change to section 4.8 - Undesirable Effects
- Change to section 10 date of revision of the text

Date of revision of text on the SPC: 01-Dec-2010

Legal Category:POM

Black Triangle (CHM): NO

Free-text change information supplied by the pharmaceutical company:

The SmPC has been updated as follows:

- minor change to section 4.2: 'children and adolescents' - heading amended to 'Paediatric Population'
- minor change to section 4.6: title changed to Fertility, pregnancy and lactation and separate section created for women of child bearing potential
- changes to section 4.8: additional common side effects included in the MedDRA table (rash, mouth and tongue irritation, pharyngolaryngeal pain and throat irritation) and a new column has also been added for side effects of unknown frequency (dysgeusia, hypersensitivity).

Updated on 12-Feb-2010 and displayed until 24-Jan-2011

Reasons for adding or updating:

- Removal of Black Triangle

Date of revision of text on the SPC: 01-Nov-2009

Legal Category:POM

Black Triangle (CHM): YES

Free-text change information supplied by the pharmaceutical company:

Removal of black triangle with effect from 03.02.2010

Updated on 16-Dec-2009 and displayed until 12-Feb-2010

Reasons for adding or updating:

- Change to section 4.2 - Posology and method of administration
- Change to section 6. 5 - Nature and Contents of Container
- Change to section 10 date of revision of the text

Date of revision of text on the SPC: 17-Nov-2009

Legal Category:POM

Black Triangle (CHM): YES

Free-text change information supplied by the pharmaceutical company:

The key changes to the SmPC are:

- To change the 1 mL ampoule ring code from three coloured rings (pink-red-red) to two coloured rings (white-yellow). This affects Section 4.2 (Posology and method of administration) and Section 6.5 (Nature and contents of container).
- Section 10 (Date of revision of the text) has been updated to 11/2009.

Updated on 22-Oct-2008 and displayed until 16-Dec-2009

Reasons for adding or updating:

- Change to section 2 - Qualitative and quantitative composition
- Change to section 4.2 - Posology and method of administration
- Change to section 4.3 - Contraindications
- Change to section 4.4 - Special warnings and precautions for Use
- Change to section 4.6 - Pregnancy and Lactation
- Change to section 4.8 - Undesirable Effects
- Change to section 5.2 - Pharmacokinetic Properties

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