

GO

[Advanced search >](#)

SPC

# Ventavis 10 microgram/ml nebuliser solution

Last Updated on eMC 14-Dec-2016 [View document](#) | Bayer plc [Contact details](#)

## Versions

[14-Dec-2016 to Current](#)[21-Nov-2016 to 14-Dec-2016](#)[11-Dec-2014 to 21-Nov-2016](#)[05-Aug-2014 to 11-Dec-2014](#)[09-Jan-2014 to 05-Aug-2014](#)[10-Sep-2013 to 09-Jan-2014](#)[25-Mar-2013 to 10-Sep-2013](#)[31-Aug-2011 to 25-Mar-2013](#)[08-Mar-2011 to 31-Aug-2011](#)[24-Jan-2011 to 08-Mar-2011](#)[12-Feb-2010 to 24-Jan-2011](#)[16-Dec-2009 to 12-Feb-2010](#)[22-Oct-2008 to 16-Dec-2009](#)[11-Feb-2008 to 22-Oct-2008](#)[18-Sep-2007 to 11-Feb-2008](#)[13-Aug-2007 to 18-Sep-2007](#)[05-Sep-2006 to 13-Aug-2007](#)[31-Jan-2006 to 05-Sep-2006](#)[22-Sep-2005 to 31-Jan-2006](#)[05-Aug-2004 to 22-Sep-2005](#)[15-Jan-2004 to 05-Aug-2004](#)

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

This site uses cookies. By continuing to browse the site you are agreeing to our policy on the use of cookies. [Continue](#)

[Find out more here.](#)

- 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 Brelib 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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.