

Medicine Shortage Communication

24 September 2025

Bronchitol, 40 mg inhalation powder, hard capsules: ongoing shortage

Dear Healthcare Professional,

Pharmaxis Europe Limited is notifying healthcare professionals about a shortage of <Bronchitol, 40 mg inhalation powder, hard capsules initiation dose assessment packs> <and> <a shortage of Bronchitol 40 mg inhalation powder, hard capsules 14-day packs>.

Overview of situation

- **Bronchitol shortages have been ongoing since 1 November 2024 in all EU/EEA member states where it is marketed. The shortages are due to distribution challenges as a result of a change of distributors and delays at the manufacturing site.**
- **The shortage affects the initiation dose assessment packs <and the 14-day dose pack.>**
- **The date of resupply is not yet known.**
- **The shortage is not due to any safety, efficacy, or quality concerns with Bronchitol.**

Mitigation measures

In order to manage the shortage, Pharmaxis Europe Limited is engaging with the European Medicines Agency and the <National Competent Authority> on mitigation measures, including the emergency supply of alternative Bronchitol 14-day packs and the manufacture of additional 14-day packs.

Regulatory authorities and healthcare providers are being informed to help ensure patients transition safely to alternative options for continuity of care.

During the shortage, healthcare professionals (HCPs) should consider the following mitigation measures:

- Healthcare professionals should not start any new patients on Bronchitol <until supplies of the Bronchitol initiation dosage assessment packs return to normal>.
 - If Bronchitol is not available, healthcare professionals should consider the need to switch existing patients to an alternative mucolytic treatment, based on existing clinical guidance.
 - Patients should remain on their standard of care treatment.
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Background on the shortage

Bronchitol, 40 mg inhalation powder, hard capsules is indicated for treatment of cystic fibrosis in adults as an add-on therapy to the best standard of care.

Bronchitol has been marketed in the following EU/EEA countries since October 2023: Austria, Czech Republic, Denmark, Germany, Greece, Hungary, Ireland, Italy, Sweden and Norway.

A change in the distributor was planned for 31 Oct 2024 but took longer than anticipated. In addition, delays in the manufacture of packaging materials to support the changeover contributed to the temporary supply interruptions.

<We are actively working to resume supply of the Bronchitol initiation dosage assessment packs as quickly as possible.>

Pharmaxis Europe regrets the impact on supply in the affected markets.

Company contact point

Further information can be obtained by contacting

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20 Rodborough, Frenchs Forest NSW 2086 Australia

Annexes

- 1.** Bronchitol Summary of Product Characteristic

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Bronchitol, mannitol 40 mg inhalation powder, hard capsules <ul style="list-style-type: none"> - initiation pack: 10 capsules + 1 inhaler - 14-day pack: 280 capsules + 2 inhalers
Marketing authorisation holder(s)	Pharmaxis Europe Limited
Purpose of the communication	Inform Healthcare professionals on Ongoing Medicine Shortage Status of Bronchitol in some of the EEA countries (Germany, Italy, Ireland, Spain) and mitigation measures to manage shortages.
MSC recipients	Target group for this letter are pharmacists and specialists that treat patients with cystic fibrosis in some EU/EEA countries in which the medicinal product is marketed. The target group can be further defined at national level, in agreement with the respective national competent authority.
Member States where the MSC will be distributed	In agreement with the national competent authorities.
Timetable	
MSC and communication plan (in English) agreed by SPOC WP	09/10/2025
MSC and communication plan (in English) agreed by MSSG	17/10/2025
Submission of translated MSCs to the national competent authorities for review	04/11/2025
Agreement of translations by national competent authorities	07/11/2025
Dissemination of MSC	14/11-2025 – 21/11/2025

Medicine Shortage Communication

24 September 2025

Bronchitol, 40 mg inhalation powder, hard capsules: ongoing marketing cessation (discontinuation)

Dear Healthcare Professional, Pharmaxis Europe Limited is notifying healthcare professionals about a discontinuation of, Bronchitol, 40 mg inhalation powder, hard capsules initiation dose assessment packs and Bronchitol 40 mg inhalation powder, hard capsules 14-day packs from October 2025 onwards.

Overview of situation

- The marketing authorisation holder decided to discontinue marketing of both, Bronchitol, 40 mg inhalation powder, hard capsules initiation dose assessment packs and Bronchitol 40 mg inhalation powder, hard capsules 14-day packs from October 2025 onwards in selected EU/EEA Member States (Austria, Czech Republic, Denmark, Greece, Hungary, Norway, and Sweden).
- This is due to challenges in establishing new distribution agreements following a distributor transition in October 2024 in the affected countries.
- The discontinuation in <insert country name> <will occur> <occurred> before/by/in/on <insert date>.
- The discontinuation is for commercial reasons and not due to any safety, efficacy, or quality concerns with Bronchitol.

Mitigation measures

In order to manage the shortage, Pharmaxis Europe Limited is engaging with the European Medicines Agency and the <National Competent Authority> on mitigation measures.

Healthcare professionals are being informed to help ensure patients transition safely to alternative options for continuity of care.

Healthcare professionals (HCPs) should consider the following mitigation measures:

- Healthcare professionals should not start new patients on Bronchitol.
 - If Bronchitol is not available, healthcare professionals should consider switching existing patients to an alternative mucolytic treatment, based on existing clinical guidance.
 - Patients should remain on their standard of care treatment.
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Background information

Bronchitol, 40 mg inhalation powder, hard capsules is indicated for treatment of cystic fibrosis in adults as an add-on therapy to the best standard of care.

Bronchitol was marketed in the following EU/EEA countries from October 2023: Austria, Czech Republic, Denmark, Germany, Greece, Hungary, Ireland, Italy, Sweden and Norway.

A change in the distributor took place in 31 Oct 2024. This changeover was not successful in Austria, Czech Republic, Denmark, Greece, Hungary, Norway, and Sweden, and Pharmaxis decided to discontinue Bronchitol in these markets due to commercial reasons.

Pharmaxis Europe regrets the impact on supply and discontinuation of supply in the affected markets.

Company contact point

Further information can be obtained by contacting

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Mobile: +61 488 838 195
Email address: regulatory@arnapharma.com
20 Rodborough, Frenchs Forest NSW 2086 Australia

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- 2.** Bronchitol Summary of Product Characteristic

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Bronchitol, mannitol 40 mg inhalation powder, hard capsules <ul style="list-style-type: none"> - initiation pack: 10 capsules + 1 inhaler - 14-day pack: 280 capsules + 2 inhalers
Marketing authorisation holder(s)	Pharmaxis Europe Limited
Purpose of the communication	Inform Healthcare professionals on discontinuation of Bronchitol in some of the EEA countries and mitigation measures to manage marketing cessation.
MSC recipients	Target group for this letter are pharmacists and specialists that treat patients with cystic fibrosis in some EU/EEA countries in which the medicinal product is marketed. The target group can be further defined at national level, in agreement with the respective national competent authority.
Member States where the MSC will be distributed	In agreement with the national competent authorities.
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