<Date>

# Direct Healthcare Professional Communication

# Ibandronic acid Accord solution for injection 3 mg/3ml in pre-filled syringe (ibandronic acid) - product packaging issues (injection needle having a shorter expiration date than the product shelf-life)

Dear Healthcare professional,

Accord healthcare, in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

## *Summary*

- **In some batches of Ibandronic acid Accord solution for injection 3 mg/3ml pre-filled syringe the injection needles included in the package have a shorter expiration date than the product shelf-life.**
- **Exposure to Ibandronic acid Accord through the expired injection needles may cause mild to moderate adverse events like tissue injury, soft tissue inflammation, injection site pain, injection site swelling and device site reactions. The physical properties of the needle might also show some changes if it is past the expiration date.**
- **According to stability data, the ibandronic acid solution in the pre-filled syringe remains stable and effective up to its defined shelf life, meaning it can be used until its expiry date without issues if the needles are replaced.**
- **The needle's expiry is independent and does not directly affect the stability or efficacy of ibandronic acid in the pre-filled syringe and has no impact on the product's quality or efficacy.**
- **Before administering Ibandronic acid Accord, check the expiry date of all the product components, including pre-filled syringe and needle. If an expired needle is identified, it should be disposed of and replaced.**

## *Background on the safety concern*

Ibandronic acid Accord solution for injection 3 mg/3ml in pre-filled syringe is indicated in adults for:

- Prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases.
- Treatment of tumour-induced hypercalcaemia with or without metastases.

A discrepancy was identified in the expiry dates between the injection needle and the product carton for one batch of Ibandronic acid Accord solution for injection 3 mg/3ml pre-filled syringe; the expiry date printed on the product carton for this batch was April 2025, whereas the expiry date of the needle was of April 2024. It was ascertained that a total of 20 batches (i.e. Batch numbers: R2200545, R2200544, R2200548, R2200551, R2200547, R2200549, R2200546, R2200550, R2200552, R2200707, R2200725, R2200724, R2200723, R2200729, R2200726, R2200742, R2200996, R2200995, R2200745 and R2201076) distributed in Austria, Lithuania, Latvia and Poland were found to have a similar discrepancy.

As a result, an investigation was conducted at the manufacturing site which confirmed that the needles included in the package had a shorter expiration date than the injection solution in the pre-filled syringe itself. The needle packed along with the product is a separate packing component and can be used up to its expiry; the needle's expiry is independent and does not directly affect the stability or efficacy of the solution in the pre-filled syringe, and has no impact on the solution’s quality or efficacy.

Furthermore, as per stability data, the ibandronic acid solution is stable and effective up to its defined shelf life and can be use up to its expiry date without detrimental issues. There was no impact on patient safety identified or reported for any of the batches of Ibandronic acid Accord solution for injection 3 mg/3ml pre-filled syringe; however, exposure to Ibandronic acid Accord solution for injection 3 mg/3ml pre-filled syringe through the expired injection needles may cause mild to moderate adverse events like tissue injury, soft tissue inflammation, injection site pain, injection site swelling and device site reactions.

Before administering Ibandronic acid Accord, the healthcare professional should check the expiry date of all the product components in the package, including the pre-filled syringe and needle. If an expired needle is identified, it should be disposed of and replaced.

## *Call for reporting*

Any suspected adverse events should be reported to {Insert details of the national spontaneous reporting system e.g. name, postal address, fax number, website} – to be completed at the local affiliate level.

## *Company contact point*

{Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address – to be completed at the local affiliate level}.

| DHPC COMMUNICATION PLAN | |
|---|---|
| **Medicinal product(s)/active substance(s)** | Ibandronic acid Accord solution for injection 3 mg/3ml pre-filled syringe |
| **Marketing authorisation holder(s)** | Accord healthcare and group of companies |
| **Safety concern and purpose of the communication** | Risk to patient safety due to the use of injection needle packed along with the pre-filled syringe having a shorter expiration date than the shelf-life of Ibandronic acid Accord solution for injection 3 mg/3ml in pre-filled syringe. |
| **DHPC recipients** | General practitioners, physicians, specialists experienced in the treatment of cancer and healthcare professionals involved in administration of Ibandronic acid Accord solution for injection 3 mg/3ml pre-filled syringe |
| **Member States where the DHPC will be distributed** | Austria, Latvia, Lithuania, Poland, The Netherlands |

| Timetable | Date |
|---|---|
| **DHPC and communication plan (in English) agreed by CHMP/CMDh** | 15 November 2024 |
| **Submission of translated DHPCs to the national competent authorities for review** | 22 November 2024 |
| **Agreement of translations by national competent authorities** | 29 November 2024 |
| **Dissemination of DHPC** | 5 December 2024 |