



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT NOTIFICATION, EL(25)A/11

Caution in Use

Issued 11 March 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Jubilant Pharmaceuticals NV

MEDICINE DETAILS

Azithromycin 250 mg Capsules

Licence: PL 19156/0138

Active Ingredient: azithromycin dihydrate

SNOMED code: 1303911000001105 (4 Cap/pack), 1135911000001109 (6 Cap/pack)

GTIN: See Table in Appendix 1

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
ZQ122005A	09/2025	4 Cap/pack	07/11/2023
ZQ122006A	09/2025	6 Cap/pack	14/02/2023
ZQ122007A	09/2025	6 Cap/pack	11/08/2023
ZQ122008A	09/2025	6 Cap/pack	08/11/2023
ZQ123003B	09/2026	6 Cap/pack	26/01/2024
ZQ123004A	09/2026	6 Cap/pack	27/02/2024
ZQ124001A	12/2026	4 Cap/pack	28/02/2024
ZQ124002A	12/2026	4 Cap/pack	24/05/2024
ZQ124003A	12/2026	4 Cap/pack	22/07/2024

ZQ124005A	07/2027	6 Cap/pack	19/12/2024
ZQ124006A	07/2027	4 Cap/pack	07/01/2025

Background

Jubilant Pharmaceuticals NV has informed the MHRA that the Patient information leaflet (PIL) in the cartons for the batches listed in the table above include an outdated PIL. These packs contain a PIL which was revised in October 2021. The latest approved PIL is dated February 2025.

The out of date PIL, revised in October 2021, is missing important updated safety information, please refer to the table in Appendix 2 for information regarding updated safety information that is included in the most recent PIL from February 2025. The latest PIL is [available on the MHRA website](#).

Advice for Healthcare Professionals:

Healthcare professionals are advised to review the information contained within this notification and take this into account when prescribing this product. When products from batches included in the table is supplied or dispensed, please ensure that patients are aware of the missing information which is summarised in the 'Advice for Patients' box below and provided in Appendix 2. As the patients would not find current PIL (dated: February 2025) in the packs, please inform the patients that the latest PIL for Azithromycin Capsules is [available on the MHRA website](#).

Advice for Patients:

Patients should continue to take medicines from the impacted batches as prescribed by your healthcare professional. This does not affect the quality of the product. There is updated safety information in the latest patient information leaflet (PIL) which accompanies the medicine. The latest PIL is [available on the MHRA website](#).

As per current PIL there is some missing information which is presented below:

What you need to know before you take Irbesartan Jubilant

- Other medicines and Azithromycin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

- Hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria): Taking these medicines at the same time

as azithromycin may increase the chance of you getting side effects that affect your heart.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Additional information:

For medical information enquiries please email safety.uk@lambda-cro.com, or telephone 0080089013370

For stock control enquiries please email JPUK.Customerservice@jubl.com, or telephone 01233 552293

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk

APPENDIX 1

Product Description	GTIN		
	Secondary pack (Mono Carton)	Shipper	Tertiary pack (Pallet)
Azithromycin 250 mg Capsules	08902805202714	18902805202711	58902805202719
Azithromycin 250 mg Capsules	08902805203063	18902805203060	58902805203068

APPENDIX 2

OLD PIL text	New PIL text
<p>2. What you need to know before you use Azithromycin</p> <p>Other medicines and Azithromycin Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.</p> <p>Tell your doctor or pharmacist if you are taking any of the following medicines:</p> <ul style="list-style-type: none"> - antacids – used for heartburn and indigestion. Azithromycin should be taken at least 1 hour before or 2 hours after the antacid - ergotamine – (used for migraine) should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain) - warfarin or similar medicines - used to thin the blood. <p>Azithromycin can thin the blood even more</p> <ul style="list-style-type: none"> - cisapride – (used to treat stomach problems) should not be taken at the same time as this may cause severe heart problems (shown on an 	<p>2. What you need to know before you use Azithromycin</p> <p>Other medicines and Azithromycin Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.</p> <p>Tell your doctor or pharmacist if you are taking any of the following medicines:</p> <ul style="list-style-type: none"> - antacids – used for heartburn and indigestion. Azithromycin should be taken at least 1 hour before or 2 hours after the antacid - ergotamine – (used for migraine) should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain) - warfarin or similar medicines - used to thin the blood. <p>Azithromycin can thin the blood even more</p> <ul style="list-style-type: none"> - cisapride – (used to treat stomach problems) should not be taken at the same time as this may cause severe heart problems (shown on

<p>electro- cardiogram or ECG machine)</p> <ul style="list-style-type: none">- terfenadine – (used to treat hay fever) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine)- zidovudine or nelfinavir – used to treat HIV infections. Taking nelfinavir with Azithromycin may mean that you get more of the side effects listed in this leaflet- rifabutin – used to treat tuberculosis (TB)- quinidine – used to treat heart rhythm problems- cyclosporin – used to stop your body rejecting an organ transplant. Your doctor will regularly check your blood levels of cyclosporin and may change your dose	<p>an electro-cardiogram or ECG machine)</p> <ul style="list-style-type: none">- terfenadine – (used to treat hay fever) should not be taken at the same time as this may cause severe heart problems (shown on an electro- cardiogram or ECG machine)- zidovudine or nelfinavir – used to treat HIV infections. Taking nelfinavir with Azithromycin may mean that you get more of the side effects listed in this leaflet- rifabutin – used to treat tuberculosis (TB)- quinidine – used to treat heart rhythm problems- cyclosporin – used to stop your body rejecting an organ transplant. Your doctor will regularly check your blood levels of cyclosporin and may change your dose- <u>Hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria): Taking these medicines at the same time as azithromycin may increase the chance of you getting side effects that affect your heart.</u>
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