

September 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Azathioprine 75 mg & 100 mg tablets Risk of overdose if wrong dose prescribed or dispensed

Dear Healthcare Professional

Resolution Chemicals Ltd in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- We wish to inform you of the launch of Azathioprine 75 mg & 100 mg tablets and new safety precautions to be taken due to this.



- These two new strengths of azathioprine are not currently available in the UK (only 25mg and 50mg have been marketed previously), therefore caution is required when prescribing and dispensing this product range to ensure that the patient receives the dose intended.
- In the event of overdose the most likely effect is bone marrow suppression. Signs and symptoms include ulceration of the throat, fever and infections. Bruising, bleeding and fatigue may occur.
- There is no specific antidote for azathioprine. In the event of overdose, blood count and hepatic function should be monitored. Azathioprine is dialysable and in severe cases dialysis may be used.

RESOLUTION

Background on the safety concern

Azathioprine is indicated in immunosuppressive regimens as an adjunct to immunosuppressive agents that form the mainstay of treatment (basic immunosuppression) including the prophylaxis of transplant rejection. Azathioprine is also indicated (either alone or in combination with corticosteroids/other drugs) in severe cases of rheumatoid arthritis, Crohn's disease, SLE, dermatomyositis, auto-immune chronic hepatitis and haemolytic anaemia, polyarteritis nodosa and chronic refractory idiopathic thrombocytopenic purpura.

Two new strengths of azathioprine have been launched in the UK, 75mg and 100mg.

These are higher in strength than azathioprine products which are currently available (25mg and 50mg).

Caution is therefore required when prescribing and dispensing this product range to ensure that the patient receives the dose intended. A photograph of each pack is provided on the previous page.

- Both new tablet strengths are light yellow, round, biconvex tablets.
- The 75 mg tablets are engraved "AZA" and "75" on one side and plain on the other side.
- The 100 mg tablets are engraved "AZA" and "100" on one side and plain on the other side.

Prescribing and dispensing errors could lead to overdose, which could cause bone marrow suppression, nadir approximately 9-19 days after dosing. The principal signs of bone marrow suppression are ulceration of the throat, fever and infections. Bruising, bleeding and fatigue may occur.

A single large dose of azathioprine is less likely to have a toxic effect than a chronic minor overdose (e.g. on prescription).

Although improvement may be delayed, it usually occurs from the twelfth day after overdose, provided that the patient has not taken a high dose in the meantime.

There is no specific antidote for azathioprine. In the event of overdose, blood count and hepatic function should be monitored. Azathioprine is dialysable and in severe cases dialysis may be used.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle
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RESOLUTION

You can report via:

- the Yellow Card website: www.yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Adverse events can also be reported to the marketing authorisation holder via the contact details below.

Company contact point

Additional information can be obtained by contacting Resolution Chemicals Ltd using the postal address, telephone number or email address below.

CONTACT DETAILS: Resolution Chemicals Limited
Wedgwood Way
Stevenage
SG1 4QT
reso@resochem.com
01438 743 900

Yours faithfully,



Penny Schenkel
Regulatory Affairs Manager
Resolution Chemicals Limited