

Safety Alert

Oct 2023

Mesalazine - risk of discolouration of urine after contact with sodium hypochlorite (bleach) & drug reaction with eosinophilia and systemic symptoms (DRESS).

EDA performs label update to include the following:

Special warnings and precautions for use

Discolouration of urine after contact with sodium hypochlorite

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach (e.g. in toilets cleaned with sodium hypochlorite contained in certain bleaches).

Severe cutaneous adverse reactions

Severe cutaneous adverse reactions (SCARs), including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment.

ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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Background:

Therapeutic indications

The treatment of:

- i) Crohn's disease localised to the colon
- ii) mild to moderate ulcerative colitis.

Crohn's disease is **an inflammatory bowel disease that causes chronic inflammation of the GI tract, which extends from your stomach all the way down to your anus.**

Ulcerative colitis is **a long-term condition where the colon and rectum become inflamed.**

References:

Medsafe ([Click here](#))