

## New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 8-11 July 2019 PRAC

### 2. Mesalazine – Nephrolithiasis (EPITT no 19405)

#### Summary of product characteristics

##### 4.4. Special warnings and precautions

Cases of nephrolithiasis have been reported with the use of mesalazine including stones with a 100% mesalazine content. It is recommended to ensure adequate fluid intake during treatment.

##### 4.8. Undesirable effects

Renal and urinary disorders

Frequency not known: nephrolithiasis\*

\* See section 4.4 for further information

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#### Package leaflet

##### 2. Warnings and precautions

Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

##### 4. Possible side effects

Not known (frequency cannot be estimated from the available data)

- kidney stones and associated kidney pain (see also section 2)