

FOI 23/891 - Docetaxel/Taxotere

Dear

Thank you for your FOI request dated 20th November 2023.

*I am gathering information about pCIA (persistent chemotherapy induced alopecia) and would like to know what data you have on reported cases of this associated with Docetaxel/Taxotere. For example;
How many cases have so far been reported
The dates they were reported*

We can confirm that the MHRA does hold the requested information and it can be accessed using the link below:

https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=UK_EXTERNAL/NONCOMBINED/UK_NON_000271632312.zip&agency=MHRA

For suspected side effects being reported for medicines, the MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs). Each iDAP contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. It is important to note that reported adverse reactions have not been proven to be related to the drug, and should not be interpreted as a list of known side effects.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Kind regards,
FOI Team
Safety & Surveillance Group
Medicines and Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

FURTHER ENQUIRY:

*Thank you for your reply.
I have looked at the link you provided but there is no mention of persistent Chemotherapy induced alopecia? Or am I missing something?*

FURTHER MHRA RESPONSE:

Dear

Alopecia is listed under the skin and subcutaneous tissue disorders heading. I have attached a screenshot showing this:

Category	Count 1	Count 2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	95	14
Nervous system disorders	416	2
Product issues	15	0
Psychiatric disorders	91	1
Renal and urinary disorders	47	0
Reproductive system and breast disorders	22	0
Respiratory, thoracic and mediastinal disorders	421	16
Skin and subcutaneous tissue disorders	523	0
Angioedema and urticaria	4	0
Cornification and dystrophic skin disorders	1	0
Epidermal and dermal conditions	381	0
Pigmentation disorders	3	0
Skin and subcutaneous tissue disorders NEC	5	0
Skin appendage conditions	129	0
Acnes	4	0
Alopecias	69	0
Alopecia	66	0
Androgenetic alopecia	3	0
Apocrine and eccrine gland disorders	9	0
Nail and nail bed conditions (excl infections and infestations)	45	0
Pilar disorders NEC	1	0

Should you require any further assistance, please do not hesitate to contact us.

Kind regards,
FOI Team