

EXCIPIENTS OF CONCERN IN OSPOLOT® 20MG/ML ORAL SUSPENSION (SULTHIAME)

Please note that this product is indicated for use in children weighing 12kg and above.1



EXCIPIENTS OF CONCERN IN OSPOLOT® 20MG/ML ORAL SUSPENSION (SUI THIAME)

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Sodium Methyl-Parahydroxybenzoate: content in mg/ml

Quantity in Ospolot 20mg/ml Oral Suspension: 2.4mg/ml

NPPG Advice: Maximum acceptable daily combined intake for methyl-hydroxybenzoates is 10mg/kg/day2

Dose in mg/kg/day	1mg/kg/day	2mg/kg/day	3mg/kg/day	4mg/kg/day	5mg/kg/day
Excipient in mg/kg	0.155mg/kg	0.23mg/kg	0.345mg/kg	0.46mg/kg	0.575mg/kg

Sodium Propyl-Parahydroxybenzoate: content in mg/ml

Quantity in Ospolot 20mg/ml Oral Suspension: 0.6mg/ml

NPPG Advice: Maximum acceptable daily propyl-hydroxybenzoate intake is 2mg/kg/day²

Dose in mg/kg/day	1mg/kg/day	2mg/kg/day	3mg/kg/day	4mg/kg/day	5mg/kg/day
Excipient in mg/kg	0.03mg/kg	0.06mg/kg	0.09mg/kg	0.12mg/kg	0.15mg/kg

Fructose: content in mg/ml

Quantity in Ospolot 20mg/ml Oral Suspension: 0.0026mg/ml

NPPG Advice: Avoid in hereditary fructose intolerance²

Dose in mg/kg/day	1mg/kg/day	2mg/kg/day	3mg/kg/day	4mg/kg/day	5mg/kg/day
Excipient in mg/kg	0.00013mg/kg	0.00026mg/kg	0.00039mg/kg	0.00052mg/kg	0.00065mg/kg

Glucose: content in mg/ml

Quantity in Ospolot 20mg/ml Oral Suspension: 0.0024mg/ml

NPPG Advice: No specific advice

Dose in mg/kg/day	1mg/kg/day	2mg/kg/day	3mg/kg/day	4mg/kg/day	5mg/kg/day
Excipient in mg/kg	0.00012mg/kg	0.00024mg/kg	0.00036mg/kg	0.00048mg/kg	0.0006mg/kg

Sucrose: content in mg/ml

Quantity in Ospolot 20mg/ml Oral Suspension: 0.0005mg/ml

NPPG Advice: Hydrolysed in the intestine to fructose and glucose; avoid in hereditary fructose intolerance²

Dose in mg/kg/day	1mg/kg/day	2mg/kg/day	3mg/kg/day	4mg/kg/day	5mg/kg/day
Excipient in mg/kg	0.000025mg/kg	0.00005mg/kg	0.000075mg/kg	0.0001mg/kg	0.00025mg/kg

Sulphur Dioxide: content in mg/ml

Quantity in Ospolot 20mg/ml Oral Suspension: 0.000004mg/ml

NPPG Advice: No advice given

Dose in mg/kg/day	1mg/kg/day	2mg/kg/day	3mg/kg/day	4mg/kg/day	5mg/kg/day
Excipient in mg/kg	0.0000002mg/kg	0.0000004mg/kg	0.0000006mg/kg	0.0000008mg/kg	0.000001mg/kg

The NPPG Position Statement on Liquid Choice which provides suggested limits of excipients can be found here:

https://nppg.org.uk/wp-content/ uploads/2020/12/Position-Statement-Liquid-Choice-V1-November-2020.pdf Or Scan the QR code





References:



For Prescribing Information, please scan the or go to

https://desitin.co.uk/pi/8KRY

UK: Adverse events should be reported.
Reporting forms and information can be found at
www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Destin Pharma Ltd.

