

Schedule 3 Ibuprofen (20mg/kg/day), max 3 days. Give **either** syrup **or** tablets **or** suppositories

Tick:	Weight of child in kg	Syrup (20 mg/ml)	Tablets (in the mouth)	Suppositories (in the bottom)
	9-11	3-4 times 2 ml		
	12-15	3-4 times 3 ml		
	16-19	3-4 times 4 ml		
	20-23	3-4 times 5 ml	3-4 times 1 tablet of 100 mg	
	24 kg	3-4 times 6 ml	3-4 times 1 tablet of 100 mg	
	25-29		3-4 times 1 tablet of 100 mg	3-4 times 1 supp of 125 mg
	30-39		3-4 times 1.5 tablet of 100 mg	3-4 times 1 supp of 125 mg
	40-49		3-4 times 1 tablet of 200 mg	3-4 times 1 supp of 125 mg

supp: suppository

If your child doesn't recover despite the treatment

If you are worried, because your son or daughter doesn't recover despite the treatment, feels drowsy or doesn't drink well, or if the earache gets worse or isn't gone after three days, you should contact your GP again.

Finally

More information about middle ear infection can be found on www.thuisarts.nl. The dosages for children in this leaflet are taken from the pharmacotherapeutic guideline for pain control ("Farmacotherapeutische richtlijn Pijnbestrijding") published by the Dutch College of General Practitioners (NHG). This leaflet is not a package insert. You can obtain more information about the medication at your pharmacy, or read more at www.consumed.nl.



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PIM-POM STUDY



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**Information leaflet about pain relief
for children with middle ear infection**

Introduction

Your GP has diagnosed your son or daughter with a middle ear infection. A middle ear infection can be very painful. The worst symptoms usually subside in two to three days. In children under the age of two, symptoms can last up to a week. The GP has given you a prescription for pain medication. In this leaflet we explain how best to give this pain medication to your child.

Paracetamol

Paracetamol alleviates the earache and suppresses the fever. It will start to work after 15 to 30 minutes, and will have an effect for 3 to 5 hours. Please wait at least 4 hours before giving the next dose of paracetamol, and at least 6 hours when you use a paracetamol suppository. Paracetamol is available as a tablet, syrup or suppository. Tablets or syrup are preferred, because paracetamol is absorbed better that way. In the first three days of the middle ear infection, it's important to give paracetamol to your child in a high dosage, following schedule 1. After three days, you decrease the dosage of paracetamol by switching to schedule 2.

Ibuprofen

For children older than 1 year with earache despite paracetamol according to schedule 1 or 2, ibuprofen may additionally be offered. Ibuprofen is stronger pain medication, which reduces the inflammation of the ear and suppresses the fever. It will start to work after 30 to 60 minutes and will have an effect for 8 hours. Wait at least 6 hours before giving the next dose of ibuprofen. Ibuprofen should **never** be given for more than three consecutive days. You will find the dosage of ibuprofen on the next page in schedule 3.

Facts about pain medicine

It's important that you give your child pain medication regularly, as instructed. This way, the amount of pain medication in the blood remains stable and the pain is reduced evenly. So don't wait until your child has an earache again, but give the next dose in time. This will also help to prevent your child waking up at night because of the pain. During the first three days, give the standard dose of paracetamol 4 to 6 times a day as a syrup **or** using tablets, **or** give a suppository 3 times a day (see schedule 1). Then gradually decrease the dosage.

Myths about pain medicine

- 'If I give painkillers too often, it will be less effective.' This is **not** true. Your child cannot become 'insensitive' to pain medicines and they are not addictive.
- 'I will save the pain medication for bedtime in the evening, that's when my child really needs it.' It's true that in most children the earache worsens in the evening; in the dark there's less distraction so the pain is more notable. But it's just as important to alleviate the pain during the day.

Schedule 1 Paracetamol (90mg/kg/day), **max** 3 days. Give **either** syrup **or** tablets **or** suppositories

Tick:	Weight of child in kg	Syrup (24 mg/ml)	Tablets (in the mouth)	Suppositories (in the bottom)
	7	4-6 times 4 ml		3 times 1 suppository of 120 mg
	8-9	4-6 times 5 ml		3 times 1 suppository of 240 mg
	10-11	4-6 times 6 ml		3 times 1 suppository of 240 mg
	12	4-6 times 7 ml		3 times 1 suppository of 240 mg
	13-14	4-6 times 8 ml		3 times 1 suppository of 240 mg
	15	4-6 times 9 ml	4-6 times 1.5 tablet of 120 mg	3 times 1 suppository of 240 mg
	16	4-6 times 10 ml	4-6 times 1.5 tablet of 120 mg	3 times 1 suppository of 240 mg
	17	4-6 times 10 ml	4-6 times 1 tablet of 250 mg	3 times 1 suppository of 500 mg
	18-19	4-6 times 11 ml	4-6 times 1 tablet of 250 mg	3 times 1 suppository of 500 mg
	20-24		4-6 times 1 tablet of 250 mg	3 times 1 suppository of 500 mg
	25-33		4-6 times 1.5 tablet of 250 mg	3 times 1 suppository of 500 mg
	34-49		4-6 times 1 tablet of 500 mg	3 times 1 suppository of 1000 mg

Schedule 2 Paracetamol (60mg/kg/day), **after** 3 days. Give **either** syrup **or** tablets **or** suppositories

Tick:	Weight of child in kg	Syrup (24 mg/ml)	Tablets (in the mouth)	Suppositories (in the bottom)
	7	4-6 times 2 ml		3 times 1 suppository of 120 mg
	8-9	4-6 times 3 ml		3 times 1 suppository of 120 mg
	10-11	4-6 times 4 ml		3 times 1 suppository of 120 mg
	12-14	4-6 times 5 ml		3 times 1 suppository of 240 mg
	15-16	4-6 times 6 ml	4-6 times 1.5 tablet of 100 mg	3 times 1 suppository of 240 mg
	17-19	4-6 times 7 ml	4-6 times 1.5 tablet of 100 mg	3 times 1 suppository of 240 mg
	20-21	4-6 times 8 ml	4-6 times 1.5 tablet of 100 mg	3 times 1 suppository of 240 mg
	22-23	4-6 times 9 ml	4-6 times 1.5 tablet of 100 mg	3 times 1 suppository of 240 mg
	24	4-6 times 10 ml	4-6 times 1.5 tablet of 100 mg	3 times 1 suppository of 240 mg
	25-37		4-6 times 1 tablet of 250 mg	3 times 1 suppository of 500 mg
	38-49		4-6 times 1.5 tablet of 250 mg	3 times 1 suppository of 500 mg

TABLE S1. ADDITIONAL BASELINE CHARACTERISTICS

Characteristic	Intervention (n=94)	Usual care (n=129)
Symptoms prior to consultation		
Runny nose*	68 (82.9)	90 (81.1)
Number of days [†]	5 (3.5-6.5)	7 (5.5-8.5)
Cough*	53 (64.6)	76 (67.9)
Number of days [†]	5 (3.5-6.5)	7 (5.5-8.5)
Sleep disturbance	69 (84.1)	92 (82.9)
Number of days [†]	2 (1-3)	4 (2-6)
Diarrhea*	14 (17.1)	22 (20.0)
Number of days [†]	3 (2-4)	3 (2-4)
Constipation*	5 (6.1)	5 (4.5)
Number of days [†]	2 (0-4)	2.5 (0.5-4.5)
Vomiting*	13 (15.9)	27 (24.5)
Number of days [†]	2 (1.5-2.5)	1 (0.5-1.5)
Decreased intake*	41 (50.0)	59 (53.6)
Number of days [†]	3 (1.5-4.5)	4 (2.5-5.5)
Abdominal pain*	19 (23.8)	29 (27.1)
Number of days [†]	2 (1-3)	2 (0.5-3.5)
Rash*	7 (8.5)	8 (7.3)
Number of days [†]	2 (0.5-3.5)	6 (4-8)
Symptoms at baseline		
Runny nose*	65 (81.3)	90 (81.8)
Cough*	51 (63.0)	73 (65.8)
Sleep disturbance*	62 (76.5)	84 (77.1)
Diarrhea*	8 (9.9)	19 (17.4)
Constipation*	3 (3.7)	1 (0.9)
Vomiting*	6 (7.4)	12 (11.0)
Decreased intake*	35 (42.7)	60 (55.0)
Abdominal pain*	15 (18.8)	19 (17.4)
Rash*	6 (7.5)	6 (5.5)

All values are numbers with percentages, unless stated otherwise

[†] median with IQR, [‡] mean with SD

*missings: prior to consultation (29-36), at baseline (31-34).

TABLE S2. CO-MEDICATION USED IN FIRST THREE DAYS

	Overall (n=201) [†]	Intervention (n=85)	Usual care (n=116)
Characteristic			
Nasal drops or spray			
<i>Sodium chloride</i>	39 (19.4)	15 (17.6)	24 (20.7)
<i>Xylometazoline</i>	28 (13.9)	16 (18.8)	12 (10.3)
<i>Otrivin</i> ®	17 (8.5)	6 (7.1)	11 (9.5)
Ear drops			
<i>Otalgan</i> ®	10 (5.0)	5 (5.9)	5 (4.3)
<i>Sofradex</i> ®	3 (1.5)	1 (1.2)	2 (1.7)
<i>Bacilcoline B</i> ®	1 (0.5)	0 (0.0)	1 (0.9)
<i>Ofloxacin</i> e	2 (1.0)	1 (1.2)	1 (0.9)
Complementary medicine	18 (9.0)	10 (11.8)	8 (6.9)
Cough syrup	6 (3.0)	2 (2.4)	4 (3.4)

All values are numbers with percentages, unless stated otherwise.

[†] Data available for 90.4% of patients in the intervention group, and 89.9% in the control group.

TABLE S3. CONSORT 2012 checklist – extension for reporting a cluster randomised trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale (for using a cluster design)	5-6, protocol
	2b	Specific objectives or hypotheses, including whether objectives pertain to the cluster level, the individual participant level or both	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio and description of how the design features apply to the clusters	5-6, protocol
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered, and whether interventions pertain to the cluster level, the individual participant level or both	6-7, protocol
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed and whether outcome measures pertain to the cluster level, the individual participant level or both	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined, including method of calculation accounting for cluster design	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction or stratification (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned. Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	6
Implementation	10a	Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	6
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	7
	10c	From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes, and how clustering was taken into account	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants and clusters who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11, Figure 1
	13b	For each group, losses and exclusions after randomisation for both clusters and individual participants, together with reasons	11, Figure 1

Recruitment	14a	Dates defining the periods of recruitment and follow-up	6,8
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for individual and cluster levels in each group	Table 1
Numbers analysed	16	For each group, number of clusters and participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11, Figure 1
Outcomes and estimation	17a	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	11-12 Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11-12 Table 3+4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-14
Other information			
Registration	23	Registration number and name of trial registry	2,16
Protocol	24	Where the full trial protocol can be accessed, if available	6, REF no. 9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3,16