

TOX/2024/43 Annex B

In this guide

[In this guide](#)

- 1. [Echinacea in the maternal diet - Introduction](#)
- 2. [Echinacea in the maternal diet - Background](#)
- 3. [Echinacea in the maternal diet - Mechanism of action](#)
- 4. [Echinacea in the maternal diet - Drug-herb interaction potential: effects on cytochrome P450 and P-glycoprotein](#)
- 5. [Echinacea in the maternal diet - Toxicity Studies](#)
- 6. [Echinacea in the maternal diet - Contaminants](#)
- 7. [Echinacea in the maternal diet - Exposure Assessment](#)
- 8. [Echinacea in the maternal diet - Risk Characterization](#)
- 9. [Echinacea in the maternal diet - Conclusions and Questions](#)
- 10. [Echinacea in the maternal diet - List of Abbreviations](#)
- 11. [Echinacea in the maternal diet - References](#)
- 12. [Echinacea in the maternal diet - TOX/2024/43 Annex A](#)
- 13. [Echinacea in the maternal diet - TOX/2024/43 Annex B](#)

Table 8a: Combined acute consumption scenarios for 4-5 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day

860 - 6,000	19 - 100	40	400 - 3,600	600 - 3,000	1,900 - 13,000
N/A	19 - 100	40	400 - 3,600	600 - 3,000	1,100 - 6,700
860 - 6,000	N/A	40	400 - 3,600	600 - 3,000	1,900 -13,000
860 - 6,000	19 - 100	N/A	400 - 3,600	600 - 3,000	1,900 - 13,000
860 - 6,000	19 - 100	40	N/A	600 - 3,000	1,500 - 9,100
860 - 6,000	19 - 100	40	400 - 3,600	N/A	1,300 - 9,700

*Rounded to 2 significant figures.

Table 8b: Combined acute consumption scenarios for 3 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
860 - 6,000	19 - 100	40	N/A	N/A	920 - 6,100
860 - 6,000	19 - 100	N/A	400 - 3,600	N/A	1,300 - 9,700
860 - 6,000	19 - 100	N/A	N/A	600 - 3,000	1,500 - 9,100

860 - 6,000	N/A	N/A	400 - 3,600	600 - 3,000	1,900 - 13,000
860 - 6,000	N/A	40	400 - 3,600	N/A	1,300 - 9,600
860 - 6,000	N/A	40	N/A	600 - 3,000	1,500 - 9,000
N/A	N/A	40	400 - 3,600	600 - 3,000	1,000 - 6,700
N/A	19 - 100	N/A	400 - 3,600	600 - 3,000	1,000 - 6,700
N/A	19 - 100	40	400 - 3,600	N/A	460 - 3,700
N/A	19 - 100	40	N/A	600 - 3,000	660 - 3,100

*Rounded to 2 significant figures.

Table 8c: Combined acute consumption scenarios for 2 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
860 - 6,000	19 - 100	N/A	N/A	N/A	900 - 6,100
860 - 6,000	N/A	40	N/A	N/A	900 - 6,000

860 - 6,000	N/A	N/A	400 - 3,600	N/A	1,300 - 9,600
860 - 6,000	N/A	N/A	N/A	600 - 3,000	1,500 - 9,600
N/A	19 - 100	40	N/A	N/A	60 - 140
N/A	19 - 100	N/A	400 - 3,600	N/A	420 - 3,700
N/A	19 - 100	N/A	N/A	600 - 3,000	620 - 3,100
N/A	N/A	40	400 - 3,600	N/A	440 - 3,600
N/A	N/A	40	N/A	600 - 3,000	640 - 3,000
N/A	N/A	N/A	400 - 3,600	600 - 3,000	1,000 - 6,600

*Rounded to 2 significant figures.

Table 9a: Combined chronic consumption scenarios for 4-5 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
580 - 4,000	10-53	40	400 - 3,600	600 - 3,000	1,600 - 11,000

N/A	10-53	40	400 - 3,600	600 - 3,000	1,100 – 6,700
580 – 4,000	N/A	40	400 - 3,600	600 - 3,000	1,600 – 11,000
580 – 4,000	10-53	N/A	400 - 3,600	600 - 3,000	1,600 – 11,000
580 – 4,000	10-53	40	N/A	600 - 3,000	1,200 – 7,100
580 – 4,000	10-53	40	400 - 3,600	N/A	1,000 – 7,700

*Rounded to 2 significant figures.

Table 9b: Combined chronic consumption scenarios for 3 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
580 – 4,000	10-53	40	N/A	N/A	600 - 4,100
580 – 4,000	10-53	N/A	400 - 3,600	N/A	1,000 – 7,700
580 – 4,000	10-53	N/A	N/A	600 - 3,000	1,200 – 7,100
580 – 4,000	N/A	N/A	400 - 3,600	600 - 3,000	1,600 –11,000

580 – 4,000	N/A	40	400 - 3,600	N/A	1,000 – 7,600
580 – 4,000	N/A	40	N/A	600 - 3,000	1,200 – 7,000
N/A	N/A	40	400 - 3,600	600 - 3,000	1,000 – 6,600
N/A	10 - 53	N/A	400 - 3,600	600 - 3,000	1,000 - 6,700
N/A	10 - 53	40	400 - 3,600	N/A	450-3,700
N/A	10 - 53	40	N/A	600 - 3,000	650-3,100

*Rounded to 2 significant figures.

Table 9c: Combined chronic consumption scenarios for 2 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
580 – 4,000	10-53	N/A	N/A	N/A	600 - 4,100
580 – 4,000	N/A	40	N/A	N/A	620 - 4,000
580 – 4,000	N/A	N/A	400 - 3,600	N/A	1,000 - 7,600
580 – 4,000	N/A	N/A	N/A	600 - 3,000	1,200 - 7,000

N/A	10-53	40	N/A	N/A	50 - 93
N/A	10-53	N/A	400 - 3,600	N/A	410 - 3,700
N/A	10-53	N/A	N/A	600 - 3,000	610 - 3,100
N/A	N/A	40	400 - 3,600	N/A	440 - 3,600
N/A	N/A	40	N/A	600 - 3,000	640 - 3,000
N/A	N/A	N/A	400 - 3,600	600 - 3,000	1,000 - 6,600

*Rounded to 2 significant figures.

Table 10: *Echinacea* products (oral dosage forms) with THR in the UK.

Product name	Dosage form	<i>Echinacea</i> species and plant part	Composition	Directions for use	Daily dose <i>Echinacea</i> (mg)
Echinaflu Soft Capsules.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench herb.	176 mg of dried pressed juice from fresh flowering herb equivalent to 3.5-4.9 g of fresh herb (DER 20-28:1).	1-2 capsules daily for no longer than 10 days.	176 - 352 mg dried pressed juice equivalent to 3.5 - 9.8 g fresh herb.

Echinacea Cold and Flu Capsules.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench) root.	140 mg dry extract from root equivalent to 838 - 1117 mg root (DER 6-8:1).	1 capsule twice a day.	280 mg dry root extract equivalent to 1,676- 2,234 mg root.
Ekinalife.	Capsules.	<i>Echinacea pallida</i> (Nutt.) Nutt. root and <i>Echinacea purpurea</i> (L.) Moench root.	200mg of <i>Echinacea pallida</i> . Nutt. and 200mg of <i>Echinacea purpurea</i> (L.) Moench powdered root.	1 capsule twice a day for no longer than 10 days.	400 mg <i>E. pallida</i> powdered root and 400 mg <i>E. purpurea</i> powdered root. Total of 1,600 mg powdered root.
Solgar Echinacea Cold and Flu Capsules.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench root.	140 mg dry extract from root equivalent to 838 - 1117 mg root (DER 6-8:1).	1 capsule twice a day for no longer than 10 days.	280 mg dry root extract equivalent to 1,676- 2,234 mg root.
Phytocold.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench root.	250 mg powdered root.	1-2 capsules three times a day fo no longer than 10 days.	750 - 1,500 mg powdered root.

Echinaflu Effervescent Tablets.	Effervescent Tablets.	<i>Echinacea purpurea</i> (L.) Moench herb.	176 mg of dried pressed juice from fresh flowering herb equivalent to 3.5-4.9 g of fresh herb (DER 20-28:1).	1-2 tablets daily for no longer than 10 days.	176 - 352 mg dried pressed juice equivalent to 3.5 - 9.8 g fresh herb.
Echineeze.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	70 mg dry extract from root equivalent to 460 - 530 mg root (DER 6.5-7.5:1).	1 tablet 3 times a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,380 - 1,590 mg root.
Echinaforce Forte Cold & Flu Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench herb and root.	1,140 mg dry extract from fresh herb (DER 1:12) and 60 mg (DER 1:11) dry extract from fresh root.	1 tablet two to three times a day for no longer than 10 days.	2,280 - 3,420 mg dry herb extract and 120-180 mg dry root extract.
Herbal Cold And Flu Relief Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	71.5 mg dry extract from root equivalent to 429 - 500 mg root (DER 6-7:1).	1-2 tablets twice daily for no longer than 10 days.	143-286 mg dry root extract equivalent to 858 - 2,000 mg root.

High Strength Herbal Cold And Flu Relief Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	143 mg dry extract from root equivalent to 858 - 1000 mg root (DER 6-7:1).	1 tablet three times a day for no longer than 10 days.	429 mg dry root extract equivalent to 2,574 - 3,000 mg root.
Echinacea Skin Care Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	71.5 mg dry extract from root equivalent to 429 - 500 mg root (DER 6-7:1).	1-2 tablets three times a day for no longer than 10 days.	143-286 mg dry root extract equivalent to 858 - 2,000 mg root.
Herbal Classics Echinacea Cold Relief Film-Coated Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	40 mg dry extract from root equivalent to 260 mg root (DER 6.5:1).	2-3 tablets three times a day.	240-360 mg dry root extract equivalent to 1,560 - 2,340 mg root.
HRI Cold And Flu Echinacea Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	56 mg dry extract from root equivalent to 338 - 450 mg root (DER 6-8:1).	1-2 tablets twice daily.	112-224 mg dry root extract equivalent to 676- 1,800 mg root.

Echinapret Coated Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench herb.	175 mg of dried pressed juice from fresh flowering herb equivalent to 6.7 - 9.8 g fresh herb (DER 38 - 56:1).	1 tablet three times a day for no longer than 10 days.	525 mg dried pressed juice equivalent to 18.4 - 29.4 mg fresh herb.
Thompson and Capper Echinacea Cold-n-Flu- Eze.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	105 mg dry extract from root equivalent to 630 - 840 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,260 - 1,680 mg root.
Fuerte Tablets.	Tablets.	Wild indigo root (<i>Baptisia tinctoria</i> (L.) R.Br.), <i>Echinacea purpurea</i> root (<i>Echinacea purpurea</i> (L.) Moench), <i>Echinacea pallida</i> root (<i>Echinacea pallida</i> (Nutt.) Nutt.), White cedar tips and leaves (<i>Thuja occidentalis</i> L.).	3.2 mg dry root extract (DER 4- 9:1) from Wild indigo root, <i>E. purpurea</i> root, <i>E. pallida</i> root and Wild cedar tips and leaves (4.92:1.85:1.85:1).	5 tablets three times a day for no longer than 10 days.	9.2 mg <i>E. pallida</i> and 9.2 mg <i>E. purpurea</i> dry root extract. Total 18.4 mg dry root extract equivalent to 73.6- 165.6 mg root.

Healthsense Echinashield Cold and Flu Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	70 mg dry extract from root equivalent to 420 - 560 mg root (DER 6-8:1).	1 tablet three times a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,260 - 1,680 mg root.
Lamberts Echinacea Cold & Flu relief tablets Nature's Best Echinacea Cold & Flu Relief tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	105 mg dry extract from root equivalent to 630 - 840 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,260 - 1,680 mg root.
Vitabiotics Echinacea Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	200 mg dry extract from root equivalent to 1200 - 1600 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	400 mg dry root extract equivalent to 2,400 - 3,200 mg root.
Potter's Skin Clear Tablets.	Tablets.	<i>Echinacea angustifolia</i> (D.C) root.	110 mg dry extract from root equivalent to 500 mg root (DER 4.5:1).	2 tablets three times a day for no longer than 10 days.	660 mg dry root extract equivalent to 2,970 mg root.

EKINACLEAR. Tablets.		<i>Echinacea purpurea</i> (L.) Moench root.	50 mg dry extract from root equivalent to 300 - 400 mg root (DER 6-8:1).	1-2 tablets three times a day for no longer than 10 days.	150-300 mg dry root extract equivalent to 900-2,400 mg root.
Lifeplan Echinacea Cold and Flu Relief Tablets.		<i>Echinacea purpurea</i> (L.) Moench root.	140 mg dry extract from root equivalent to 840 - 1120 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	150-300 mg dry root extract equivalent to 900-2,400 mg root.
Echinaforce Chewable Cold & Flu Tablets.	Chewable tablets.	<i>Echinacea purpurea</i> (L.) Moench herb and root.	380 mg dry extract from fresh herb (DER 1:12) and 20 mg dry extract (DER 1:11) from fresh root.	2 tablets two to three times a day for no longer than 10 days.	1,520 - 2,280 mg dry herb extract and 80-120 mg dry root extract.
Herbal Cold And Flu Sachets.	Sachets.	<i>Echinacea purpurea</i> (L.) Moench root.	71.5 mg dry extract from root equivalent to 429 - 500 mg root (DER 6-7:1).	1 sachet three times a day for no longer than 10 days.	214.5 mg dry root extract equivalent to 1,287-1,500 mg root.

Cystorelief Cystitis Uva- ursi & Echinacea oral drops ^a .	Tincture.	<i>Echinacea purpurea</i> (L.) Moench herb, Uva-ursi herb (<i>Arctostaphylos</i> <i>uva-ursi</i> (L.) Spreng, Herb).	240 mg of tincture from fresh herb (DER 1:12) per 1 ml.	15 drops in a little water 2-5 times daily. 1mL is equivalent to 30 drops.	240-600 mg of tincture from fresh herb.
Potter's Elixir of Echinacea Plus/Napiers Elixir of Echinacea Complex ^b .	Oral solution.	<i>Echinacea angustifolia</i> (D.C) root, Wild Indigo root, Fumitory herb.	0.64 mL liquid extract from root equivalent to 640 mg root per 5 mL (DER 1:1).	5 mL three times a day for no longer than 10 days.	1.92 mL liquid root extract equivalent to 1.92 g root.
Echinacin Juice MADAUS.	Oral solution.	<i>Echinacea purpurea</i> (L.) Moench) herb.	117 mg of dried pressed juice from fresh flowering herb equivalent to 3.7 - 6.3 g of fresh herb per 5 mL (DER 31.5-53.6:1).	5 mL three times a day for no longer than 10 days.	351 mg dried pressed juice equivalent to 11.1 - 18.9 g fresh herb.
Echinacin Liquidum MADAUS ^c .	Oral solution.	<i>Echinacea purpurea</i> (L.) Moench) herb.	1.99 g of pressed juice from fresh flowering herb equivalent to 3.4 - 5 g of fresh herb per 2.5 mL (DER 1.7-2.5:1).	2.5 mL three times a day for no longer than 10 days.	5,970 mg pressed juice equivalent to 10.2-15 g fresh herb.

Echinaforce hot drink cold & flu echinacea concentrate for oral solution.	Tincture.	<i>Echinacea purpurea</i> (L.) Moench herb and root.	1,140 mg extract (as tincture) from fresh herb (DER 1:12-13) and 60 mg extract (as tincture) from fresh root (DER 1:11-12) per 5 ml.	Days 1-3: Take 5 ml diluted in hot water five times daily. Days 4-10: Take 5 ml diluted in hot water three times daily.	3,420 - 5,700 mg herb extract (tincture) and 180- 300 mg root extract (tincture).
Echinaforce Sore Throat Spray ^d .	Oromucosal spray.	<i>Echinacea purpurea</i> (L.) Moench herb and root, Sage leaves, (<i>Salvia officinalis</i> L. <i>folium</i>).	863.3 mg tincture from fresh herb (DER 1:12) and 45.5 mg tincture from fresh root (DER 1:11) per 1 mL.	1 spray (0.22 mL) six to ten times a day for no more than 7 days.	1,147 - 1,910 mg herb tincture and 60 - 100 mg root tincture.
Duchy Herbals Echina-Relief Tincture ^e .	Tincture.	<i>Echinacea purpurea</i> (L.) Moench root.	1mL of tincture from dried root (1:3) (equivalent to 33 mg dried root) per 1 mL tincture.	2.5 ml of tincture, in water, two or three times daily for no longer than 10 days.	5-7.5 mL tincture equivalent to 165 - 248 mg dried root.

a 1 mL contains 426 mg ethanol equivalent to 10.8 mL beer or 4.5 mL wine (43% v/v ethanol content).

b 5 mL contains 760 mg ethanol equivalent to 19 mL beer or 7.9 mL wine (19 % v/v ethanol content).

c 1 mL contains 179 mg ethanol equivalent to 4 mL beer or 1.6 mL wine (18% v/v ethanol content).

d 1 mL contains 370 mg ethanol equivalent to 8.4 mL beer or 3.4 mL wine (38-42% v/v ethanol content).

e 2.5 mL contains 900 mg ethanol equivalent to 23 mL beer or 10 mL wine (38-45% v/v ethanol content).

Table 11: Summary of doses and preparations of THR products in the UK and EMA monographs.

<i>Echinacea</i> species	Daily dose THR products UK	EMA monographs daily doses
	Pressed juice from herb (DER 1.7-2.5:1): 5,970 mg (equivalent to 10.2-15 g fresh herb).	Pressed juice from herb (DER 1.5-2.5:1): 6 - 9 g (equivalent to 9 - 22.5 g fresh herb.).
	Dried pressed juice from herb (DER 20-28:1): 176-352 mg (equivalent to 3.5 - 9.8 g fresh herb)	Dried pressed juice: Corresponding to the expressed juice above.
<i>Echinacea purpurea.</i>	Dry root extract (DER 6-7:1): 143 - 429 mg (equivalent to 858 - 3,000 mg root) Powdered root: 250 -1500 mg.	(EMA monograph, 2014). Dry root extract (DER 5.5-7.5:1): 360 mg (equivalent to 1,980 - 2,700 mg root). (EMA monograph, 2017).

		Powdered root: 500-1,500 mg.
	Dry root extract (DER 4.5:1): 660 mg equivalent to 2,970 mg root.	Liquid root extract (DER 1:1): 0.75 - 3 mL (equivalent to 750 -3,000 mg root).
<i>Echinacea angustifolia.</i>	Liquid root extract (DER 1:1): 1.92 mL (equivalent to 1,920 mg root).	Tincture (DER 5:1): 3-6 mL (equivalent to 1,500 - 3,000 mg root).
		(EMA monograph 2018).
	Dry root extract (DER 4-9:1): 9.2 mg <i>E. pallida</i> and 9.2 mg <i>E. purpurea</i> (equivalent to 36.8-82.8 mg root).	Dry root extract (DER 4-8:1): 90-96 mg (equivalent to 360 - 786 mg root).
<i>Echinacea pallida.</i>	Powdered root: 400 mg <i>E. pallida</i> and 400 mg <i>E. purpurea</i> .	(EMA monograph 2012).