

Exposure Assessment

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](#)

148. Echinacea is not used as a food commodity on its own or in recipes for cooking, but there are tea and honey products, found from online sources, supplemented with Echinacea and Echinacea extracts (Table 3), and these could be consumed as part of the general diet. Data from the National Diet and Nutrition Survey (NDNS) (Bates et al., 2014, 2016, 2020; Roberts et al., 2018) on acute herbal and fruit tea consumption and honey among women of childbearing age (16-49 years) may provide an indicator of Echinacea intake from these foods during pregnancy. The NDNS does not provide data for pregnant or lactating women, so while data is based on women of childbearing age, this may not necessarily be representative of the maternal diet. It is also worth noting that some of the Echinacea containing tea products advise pregnant or lactating women to consult a healthcare professional prior to using the product. The Echinacea-containing honey states that it is suitable for pregnant or breastfeeding women, whilst the lozenges contain no warnings. Like tablets and

capsules lozenges are solid dosage forms, but they are specifically designed to dissolve or disintegrate slowly in the mouth and are formulated with a flavoured or sweetened base.

Table 3: Food products containing *Echinacea*.

Product name	Type	<i>Echinacea</i> species and plant part	Composition	Directions for use	Daily dose of <i>Echinacea</i> (mg)	Additional information, warnings
Pukka Herbs Elderberry and Echinacea Organic Herbal Tea.	Tea bags.	<i>Echinacea</i> (species not specified) herb.	Ginger root, liquorice root, <i>Echinacea</i> herb (11%) , beetroot, aniseed, rosehip, peppermint leaf, orange peel, elderflower (5%), elderberry (4%), hibiscus, orange essential oil flavour, blackcurrant flavour.	Not specified.	Not specified.	None.

Yogi Tea Echinacea Special Formula.	Tea bags.	Not specified.	Cinnamon, Echinacea , ginger, fennel, rooibos, roasted chicory, carob, cardamom, basil, burdock root, black pepper, turmeric root, astragalus, vanilla beans.	Pour 250 ml of freshly boiled water over the teabag. Allow to infuse for 5 to 6 minutes - or longer for a stronger flavour.	Not specified.	None.
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<p>Yogi Tea, Echinacea Immune Support, Caffeine Free, 16 Tea Bags, 0.85 oz (24 g).</p>	<p>Tea bags.</p>	<p><i>Echinacea purpurea</i> Plant part not specified.</p>	<p>Each tea bag contains: 144 mg <i>Echinacea purpurea</i>, 47 mg <i>Echinacea purpurea</i> extract, 1,245 mg herb blend (rose hips, dried acerola juice, basil, cinnamon, ginger, cardamom, elderberries, black pepper, moringa, hibiscus, cocoa shells, liquorice, fennel).</p>	<p>Bring water to boiling and steep 7 minutes. For a stronger tea, use 2 tea bags. Drink 3-4 cups daily.</p>	<p>432 - 1,152 mg <i>Echinacea purpurea</i> and 141 - 376 mg <i>Echinacea purpurea</i> extract.</p>	<p>Consult your healthcare provider prior to use if pregnant or nursing, or taking any medication or have a medical condition.</p>
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Traditional Medicinals, Organic Echinacea Plus, Elderberry, Caffeine Free, 16 Wrapped Tea Bags, 0.85 oz (24 g).

Tea bags. *Echinacea purpurea* herb.

Each tea bag contains:

1005 mg
Echinacea purpurea
herb,

127.5 mg

European elder flower, 1,245 mg herb blend (ginger rhizome, chamomile flower, yarrow flower, peppermint leaf,

Echinacea purpurea root dry extract (2-8:1), European elder fruit dry concentrate).

Pour 8 oz (~227 mL) freshly boiled water over 1 tea bag. Cover & Steep for 10-15 min. Enjoy 5-6 cups throughout the day.

5,025 - 6,030 mg *Echinacea purpurea* herb.

Do not use if pregnant or breastfeeding. Directed other your healthcare practitioner. Not recommended with children 12 years of age.

Traditional Medicinals, Organic Immune Zoom®, Lemon Ginger Echinacea, Caffeine Free, 16 Wrapped Tea Bags, 1.13 oz (32 g).

Tea bags. *Echinacea purpurea* root.

2,000 mg herb blend (ginger rhizome, ***Echinacea purpurea*** herb, lemon myrtle leaf (*Backhousia citriodora*), lemon peel, liquorice root, peppermint leaf, ***Echinacea purpurea*** root dry extract (2-8:1), cardamom seed, Organic liquorice root dry extract (6:1).

Pour 8 oz (~227 mL) freshly boiled water over 1 tea bag. Cover & Steep for 10-15 min. Enjoy 2 cups throughout the day.

Not specified.

Consult your healthcare practitioner prior to use if you are pregnant or breastfeeding, if you have an autoimmune or immune system disorder, or if you are taking immunosuppressants or if you have a gallbladder disorder. Not recommended for use with children under 12 years of age.

Superblends Defence 20 Tea Bags.	Tea bags.	<i>Echinacea</i> (species not specified) root.	Green tea (26%), Ginger root (15%), White hibiscus, Cinnamon bark, Natural lemon Flavouring with other Natural Flavourings (10%), <i>Echinacea</i> root (9%), Lemon peel (5%), Natural flavouring, Natural lime flavouring (4%), vitamin C (2%).	At least 1 cup a day.	Not specified.	None.
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Frontier Co- op, Organic Cut & Sifted <i>Echinacea</i> <i>Angustifolia</i> Root.	Loose herb for tea.	<i>Echinacea</i> <i>angustifolia</i> root.	Half a teaspoon contains 1.1 g cut root.	To prepare as tea, pour 8 oz. (~227 mL) boiling water over 1/2 teaspoon of root. Cover and steep 20-30 minutes, strain and serve immediately.	Not specified.	If pregnant, n suffering from medical condi taking medica consult a hea practitioner b use.
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Frontier Co-op, Organic Elderberry Echinacea Wellness Tea, 16 oz.	Loose herb for tea.	<i>Echinacea purpurea</i> herb and root.	Elderberry, <i>Echinacea purpurea</i> herb, peppermint, yarrow, ginger, chamomile flower, <i>Echinacea purpurea</i> root.	Pour 8 oz. (227 mL) boiling water over 1 tablespoon of tea. Cover and steep 10-15 minutes, strain and serve immediately.	Not specified.	If pregnant, not suffering from medical conditions, taking medication, consult a health practitioner before use.
Frontier Co-op, Cut & Sifted Echinacea Purpurea Herb.	Loose herb for tea.	<i>Echinacea purpurea</i> herb.	One teaspoon contains 820 mg <i>Echinacea purpurea</i> cut herb.	To prepare as a tea, pour 8 oz. (~227 mL) boiling water over 1 teaspoon of herb. Cover and steep 3-5 minutes, strain and serve immediately.	Not specified.	None.

Lemon & Ginger Vitamin Honey.	Honey.	Not specified.	<p>1 teaspoon (7g) contains:</p> <p>15 mg Echinacea, 3 mcg vitamin D3, 10mg vitamin C, 0.4 mcg vitamin B6, 0.4 mcg vitamin B12.</p>	2 teaspoons into warm water.	Not specified.	<p>This product is suitable for pre or breastfeeding women, however we'd always recommend to consult with a professional if you are unsure before making a purchase.</p>
Orange Vitamin Honey.	Honey.	Not specified.	<p>1 teaspoon contains:</p> <p>15 mg Echinacea, 3 mcg vitamin D3, 10mg vitamin C, 0.4 mcg vitamin B6, 0.4 mcg vitamin B12.</p>	2 teaspoons into warm water.	Not specified.	<p>This product is suitable for pre or breastfeeding women, however we'd always recommend to consult with a professional if you are unsure before making a purchase.</p>
Wedderspoon Natural Manuka Honey and Ginger with Echinacea Drops (20 Drops per box).	Honey.	Not specified.	<p>Organic cane sugar, organic manuka honey (15.5%), organic brown rice syrup, ground ginger (0.6%), Echinacea (0.04%).</p>	Not specified.	Not specified.	None.

A.Vogel
Echinacea
Lozenges |
Extract of
Freshly
Harvested
Echinacea |
Blend of
Other Herbs |
Suitable for
Vegetarians |
30g.

Lozenges.

*Echinacea
purpurea*
herb and
root
extract.

Each lozenge
(2.2 g)
contains:

Glucose
syrup, raw
cane sugar,
honey, herb
extracts,
fresh
**Echinacea
purpurea
extract
(0.62%)**,
natural
flavours,
caramel
colour,
menthol,
peppermint
essential oil,
citric acid.

As required.

Not
specified.

None.

Honey Lemon Echinacea Soothe & Clear Drops 75g (Ricola).	Lozenges.	<i>Echinacea</i> (species not specified) dry pressed juice.	Sugar, glucose syrup, Fair Trade honey (5.1%), extract (0.5%) of Ricola's herb mixture, vitamin C, lemon juice concentrate, acid (citric acid, malic acid), natural flavourings, natural <i>Echinacea</i> aroma (<i>Echinacea</i> dry pressed juice), mint oil, peppermint oil, menthol.	As required.	Not specified.	None.
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Swanson, Zinc & C with Elderberry & Echinacea, Orange & Lemon, 60 Lozenges.	Lozenges.	<i>Echinacea purpurea</i> herb (aerial parts) powder.	Each lozenge contains: 100 mg vitamin C, 25 mg zinc, 20 mg Echinacea purpurea powder , 20 mg elderberry extract.	As a dietary supplement, 40 mg dissolve one lozenge in the mouth two times per day.	<i>Echinacea purpurea</i> powdered herb.
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149. The NDNS data suggests that women of childbearing age consume a mean of 520 mL/person/day or 1,500 mL/person/day at the 97.5th percentile of herbal and fruit tea at the acute consumption level (Table 4a). This corresponds to a mean of 5.2 g/person/day or 15 g/person/day of fruit and herbal tea at the 97.5th percentile on a dried basis (calculated by applying a conversion factor of 0.01 to convert tea as consumed to dry weight; Table 4b). At the chronic consumption level, women of childbearing age consume a mean of 290 mL/person/day or 1,100 mL/person/day at the 97.5th percentile (Table 4a), corresponding to 2.9 g/person/day or 11 g/person/day respectively on a dried basis (Table 4b).

150. Information from Echinacea tea products available suggests preparing the teacup with 227-250 mL hot water and consumption recommendations vary between 2-6 cups per day (Table 3). Based on the Echinacea content of the tea products (Table 3), that would provide 144 - 1005 mg herb per cup of tea. Taking the NDNS data into consideration and the assumption that a cup of Echinacea tea will be prepared with 250 mL water, this would equate to the consumption of 6 Echinacea cups of tea per day at the 97.5th percentile by women of childbearing age at the acute consumption level, corresponding to 864 - 6,030 mg Echinacea herb. At the chronic consumption level, approximately 4 cups of tea per day will be consumed at the 97.5th percentile, corresponding to 576 - 4,020 mg Echinacea herb.

Table 4a: Acute and chronic consumption of herbal and fruit tea (as consumed) as a proxy for Echinacea tea (without recipes).

Consumption	Consumers (n)[^]	Mean (mL/person /day)	97.5th percentile (mL/person /day)	Mean (mL/kg/ bw/day)	97.5th percentile (mL/kg bw/day)	Respondents in population group (n)
Acute	364	520	1,500	8.0	23	2,556
Chronic	364	290	1,100	4.5	16	2,556

*Rounded to 2 significant figures.

[^]Based on women of childbearing age (16-49 years).

a Conversion factor of 0.99 used to convert tea dry weight to 'as consumed'.

Table 4b: Acute and chronic consumption of herbal and fruit tea (dry weight) as a proxy for Echinacea tea (without recipes).

Consumption	Consumers (n)[^]	Mean (mL/person /day)	97.5th percentile (mL/person /day)	Mean (mL/kg/ bw/day)	97.5th percentile (mL/kg bw/day)	Respondents in population group (n)
Acute	364	5.2	15	0.08	0.23	2,556
Chronic	364	2.9	11	0.045	0.16	2,556

*Rounded to 2 significant figures.

[^]Based on women of childbearing age (16-49 years).

a Conversion factor of 0.01 used to convert tea from 'as consumed' to dry weight.

151. The NDNS data on honey consumption (Table 5) suggests that women of childbearing age have an acute consumption of honey with a mean of 15 g/person/day honey or 48 g/person/day at the 97.5th percentile. Under the chronic consumption scenarios, these figures are a mean of 6 g/person/day honey

or 25 g/person/day at the 97.5th percentile. Echinacea honey products contain 0.4-2.1 mg Echinacea per 1 g honey (Table 3). This would equate to the consumption of 19.2-101 mg Echinacea at the 97.5th percentile for acute consumption and 10-52.5 mg Echinacea under the chronic consumption scenario.

Table 5: Acute and chronic consumption of honey as a proxy for *Echinacea* honey consumption (without recipes).

Consumption	Consumers (n)^	Mean (g/person /day)	97.5th percentile (g/person /day)	Mean (g/kg/ bw/day)	97.5th percentile in (g/kg bw/day)	Respondents population group (n)
Acute	293	15	48	0.23	0.75	2,556
Chronic	293	6.0	25	0.093	0.35	2,556

*Rounded to 2 significant figures.

^Based on women of childbearing age (16-49 years).

152. Echinacea supplements found online are available as solid dosage forms such as tablets and capsules (Table 6a) and oral liquids such as oral solutions and tinctures (Table 6b). The majority of these supplements advise consultation with a healthcare provider prior to using them if pregnant/breastfeeding or state that they are not suitable for use in pregnancy and lactation. In addition, some of the supplements recommend short-term use only (5 days to several weeks).

Table 6a: Echinacea food supplements (solid dosage forms).

Product name	Dosage form	<i>Echinacea</i> species and plant part	Composition	Directions for use	Daily dose <i>Echinacea</i> (mg)	Additional information
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NOW Foods
Echinacea
400 mg 100
Veg
Capsules.

Echinacea
Capsules. *purpurea*
root.

400 mg root.

Take 2
capsules 1 to
4 times daily
as needed.
Continuous
high level
consumption
of this product
for more than
2 weeks of
each month is
not
recommended.

800 - 3,200
mg root.

For adults
Consult p
if
pregnant,
taking
medication
have a m
condition.

Grape Tree
Echinacea
Root 500mg.

Tablets. *Echinacea*
(species not
specified)
root.

500 mg root.

1 tablet daily.

500 mg
root.

Linked to
health be
including
inflamma
improved
immunity
lower bloo
levels.

Swanson
Echinacea,
400mg
herbal
supplement.

Capsules.

*Echinacea
purpurea*
herb (aerial
parts).

400 mg herb.

1 capsule up
to 3 times per
day. Limit use
to eight
consecutive
weeks. Use
periodically for
a few weeks at
a time (for
maintenance
purposes).

400-1,200
mg herb.

For adults
Do not take
product if
pregnant
nursing. C
your heal
provider b
using this
product if
taking
medication
have a m
condition,
especially
autoimmu
condition.

Echinacea,
1300 mg (per
serving), 180
Vegetarian
Capsules.

Capsules.

*Echinacea
purpurea*
herb (aerial
parts).

65 mg herb
extract (DER
10:1)
equivalent to
650 mg herb.

Take 2
vegetarian
capsules per
day preferably
with a meal.

130 mg
herb
extract
equivalent
to 1,300 mg
herb.

If you are
pregnant,
nursing, t
any medic
or have a
medical
conditions
consult yo
doctor be
use.

Life Extension, Echinacea Elite, 60 Vegetarian Capsules.	Capsules.	<i>Echinacea purpurea</i> herb and <i>Echinacea angustifolia</i> root.	<i>Echinacea purpurea</i> (aerial parts) extract 125 mg [standardised to 4% phenolic compounds]. <i>Echinacea angustifolia</i> (root) extract 125 mg [standardised to 4% echinacosides]	Take 1 capsule twice daily.	250 mg <i>Echinacea purpurea</i> (aerial parts) extract and 250 mg <i>Echinacea angustifolia</i> (root) extract.	Consult with physician are under treatment medical c or if you a pregnant lactating.
Specialist Herbal Supplies (SHS) Echinacea Capsules.	Capsules.	<i>Echinacea angustifolia</i> .	325 mg. Preparation not specified..	1 capsule, 3 times a day, taken with food or a drink. If desired, up to four times this amount can safely be taken.	975-1,300 mg <i>Echinacea angustifolia</i> .	If you are pregnant, feeding, h medical c or are un medical supervision please co doctor be use.

Nuke Nutrition Echinacea Tablets High Strength x180 - Immune Support Echinacea Herbal Supplements.	Tablets.	<i>Echinacea.</i> Species and part of plant not specified.	200 mg extract (DER 10:1) equivalent to 2,000 mg <i>Echinacea.</i>	Take 1 tablet with your first meal of the day.	200 mg extract equivalent to 2,000 mg <i>Echinacea.</i>	Consult y physician are taking medication under me supervisi you are p and breastfee
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Echinacea Extract Capsules 3500mg (High Strength) Echinacea <i>purpurea.</i>	Capsules.	<i>Echinacea purpurea.</i> Plant part not specified.	350 mg extract (DER 10:1) equivalent to 3,500 mg <i>Echinacea pupurea.</i>	Take 1 capsule per day with water.	350 mg extract equivalent to 3,500 mg <i>Echinacea purpurea.</i>	None.
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<p>Nature's Way, Echinacea Goldenseal, 450 mg, 100 Vegan Capsules.</p>	<p>Capsules.</p>	<p><i>Echinacea purpurea</i> herb (aerial parts) and <i>Echinacea angustifolia</i> root.</p>	<p>450 mg <i>Echinacea 7</i> Herb Blend: <i>Echinacea purpurea</i> (stem, leaf, flower), Goldenseal (root), <i>Echinacea angustifolia</i> (root), Burdock (root), Gentian (root), Cayenne Pepper (fruit), Wood Betony (stem, leaf, flower).</p>	<p>Take 2 capsules twice daily, preferably with food.</p>	<p>1,800 mg <i>Echinacea 7</i> herb blend. Exact dose of <i>Echinacea</i> cannot be determined.</p>	<p>Do not use if you are pregnant or nursing, have a stomach or duodenal ulcer, or inflammation of the stomach. Not recommended for individuals with autoimmune conditions. If you have diabetes or are taking medication, consult a healthcare professional before use.</p>
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<p>Nature's Way, Echinacea Purpurea Herb, 1,200 mg, 180 Vegan Capsules (400 mg per Capsule).</p>	<p>Capsules.</p>	<p><i>Echinacea purpurea</i> herb (aerial parts).</p>	<p>400 mg herb.</p>	<p>Adults take 3 capsules three times daily, preferably with food. Only take this supplement if they are suffering from a severe illness to stimulate the immune system and do not take for longer than 5 days.</p>	<p>3,600 mg herb.</p>	<p>If pregnant or nursing, or taking any medication, consult a healthcare professional before use.</p>
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California Gold Nutrition, EuroHerbs, Echinacea Herb Extract, Euromed Quality, 80 mg, 180 Veggie Capsules.	Capsules.	<i>Echinacea purpurea</i> herb (aerial parts).	80 mg <i>Echinacea purpurea</i> (aerial parts) extract (DER 5:1) equivalent to 400 mg dried herb.	Take 1 capsule daily, with food.	80 mg extract equivalent to 400 mg dried herb.	Pregnant lactating should consult with a pharmacist naturopath or other qualified healthcare professional to taking supplements.
21st Century, Echinacea Complex, 250 mg, 60 Vegetarian Capsules (125 mg per Capsule).	Capsules.	<i>Echinacea purpurea</i> herb and <i>Echinacea angustifolia</i> root.	125 mg <i>Echinacea</i> blend (<i>Echinacea purpurea</i> herb extract and <i>Echinacea angustifolia</i> root powder).	Adults take two (2) capsules daily with any meal or as directed by a healthcare provider.	250 mg <i>Echinacea</i> blend (<i>Echinacea purpurea</i> herb extract & <i>Echinacea angustifolia</i> root powder).	Consult a healthcare provider prior to use if pregnant, nursing, or on medication. Have a medical condition or planning a medical procedure.
Sundown Naturals, Whole Herb Echinacea, 400 mg, capsules.	Capsules.	<i>Echinacea purpurea</i> herb (aerial parts).	400 mg <i>Echinacea purpurea</i> herb.	Take (1) capsule seven times daily, preferably with meals. Capsules may be opened and prepared as a tea.	2,800 mg herb.	If you are pregnant, nursing, taking any medication or have a medical condition, consult your doctor before.

Gaia Herbs, Echinacea Goldenseal, 60 Vegan Liquid Phyto- Caps.	Capsules.	<i>Echinacea purpurea</i> root, aerial parts and seed and <i>Echinacea angustifolia</i> root.	800 mg Proprietary Extract Blend: <i>Echinacea purpurea</i> root, Goldenseal (<i>Hydrastis canadensis</i>) root, <i>Echinacea angustifolia</i> root, <i>Echinacea purpurea</i> seed, St. John's Wort (<i>Hypericum perforatum</i>) aerial parts, <i>Echinacea purpurea</i> aerial parts.	Adults take 2 capsules 3 times daily between meals.	4,800 mg Proprietary Extract Blend. Exact dose of <i>Echinacea</i> cannot be determined.	Not for use during pre- or lactation
Specialist Herbal Supplies (Shs) Echinacea Compound.	Capsules.	<i>Echinacea angustifolia.</i>	<i>Echinacea angustifolia</i> 92mg, Garlic 92mg, Myrrh 92mg, Wild Indigo 46mg. <i>Echinacea</i> preparation not specified.	1 capsule, 3 times a day, taken with food or a drink.	276 mg <i>Echinacea angustifolia.</i>	Do not take alongside thinning or such as w Not to be pregnanc breastfee for childre under 12 old.

Table 6b: *Echinacea* food supplements (oral liquids).

Product name	Dosage form	<i>Echinacea</i> species and plant part	Composition	Directions for use	Daily dose <i>Echinacea</i> (mg)	Additional information
Nature's Way, Echinacea, 500 mg, 1 fl oz (30 mL).	Oral solution.	<i>Echinacea purpurea</i> herb (aerial parts).	250 mg herb extract per 1 mL.	Adults: Take 2 mL 3 times daily. Children ages 6-12 years of age: Take 1 mL 3 times daily. Intensive: Take 2 mL every 2 hours for first 48 hours. Then take 2 mL 3 times daily for next 8-9 days. May be added to foods/drinks.	Adults: 500-1,500 mg herb extract Children: 250-750 mg herb extract.	If pregnant, nursing, or taking any medications, consult a healthcare professional before use. Not recommended for individuals with autoimmune conditions.
Echinacea Single Herbal Tincture 150mL.	Tincture.	<i>Echinacea</i> (species not specified).	Dried herb to liquid ratio W/V 1:5 or fresh herb to liquid ratio W/V 1:3.	Dosage is normally between 1mL and 5 mL added to a little water up to three times a day.	3 - 15 mL herb extract daily equivalent to 600 - 3,000 mg dried herb or 1,000 - 5,000 mg fresh herb.	None.

Baldwins Echinacea (angustifolia) Herbal Tincture.	Tincture.	<i>Echinacea angustifolia.</i>	Herb:Liquid 1:3.	No guidance.	No guidance.	None.
Napiers the Herbalists Napier's Organic Echinacea Drops.	Oral drops	<i>Echinacea purpurea</i> herb (aerial parts)	Not stated	Take 15-20 drops 2-3 times a day. 15 drops = 0.5 mL	30 - 60 drops daily. Equivalent to 1-2 mL solution.	Not suitable for children under 12 years. Do not take if pregnant or breastfeeding.
100% Organic Echinacea Tincture Viridian 50ml.	Tincture.	<i>Echinacea purpurea</i> whole plant.	1 mL = 480 mg whole fresh plant.	Take 15 - 30 drops, 2-3 times daily in a little fruit juice or water. 15 drops = 0.5 mL.	31 - 60 drops daily. Equivalent to 1-2 mL solution or 480 - 960 mg fresh plant.	Not to be used during pregnancy or lactation unless recommended by a healthcare practitioner.

NOW Foods, Echinacea Extract, 2 fl oz (59 ml).	Oral solution.	<i>Echinacea angustifolia</i> and <i>Echinacea purpurea</i> root.	Root extract. 1.6 mL per 2 droppersfuls.	Take 1 to 2 droppersful in tea or water 1 to 3 times daily as needed. Continuous high-level consumption of this product for more than 2 weeks of each month is not recommended.	0.8 - 4.8 mL.	Not recommended for pregnant or nursing women.
Cytoplant Organic Echinacea.	Oral solution.	<i>Echinacea angustifolia</i> .	1:3 extract.	Take 20 drops mixed into water or liquid of choice 2-3 times daily. 20 drops = 2mL.	40-60 drops daily. Equivalent to 4-6 mL extract daily.	Not suitable for children under 12 years of age. Not suitable for use whilst pregnant or breastfeeding.

153. If the supplements are composed of herbal blends or don't specify directions for use or preparation type, the recommended daily dose of Echinacea is difficult to derive. Where extracts are used in preparations, the daily dose of Echinacea from capsules/tablets (Table 6a) is 130 - 700 mg dry herb extract (equivalent to 1,300 - 7,000 mg herb). For tablets/capsules containing dried plant parts (herb or root), the dose of Echinacea is 400 - 3,600 mg (herb) or 500 - 3,200 mg (root). Fewer oral liquid products were found from online sources and the directions for use, or the exact composition was lacking for some (Table 6b). From the liquid products available, the daily Echinacea dose is 500 - 1,500 mg herb extract or 600 - 3,000 mg dried herb.

154. The Echinacea products for oral use with THR from the MHRA are available as tablets, capsules, oral solutions, tinctures and oromucosal spray (see Table 10

Annex B). The most common products with THR in the UK are tablets and capsules based on dry extract from *E. purpurea* root, with daily doses of 143-429 mg dry root extract (equivalent to 858 – 3,000 mg root). If THR preparations (available in both solid and liquid dosage forms) made with dried pressed juice from *E. purpurea* herb are consumed, the daily dose would be 176-352 mg dried pressed juice (equivalent to 3.5-9.8 g fresh herb). A comparison between the THR products and the EMA monographs in terms of species used, preparations and doses can be found in Table 11, Annex B. There is no evidence to suggest that THR products and Echinacea food supplements are taken together, and the assumption is that this is unlikely, especially since the THR products advise against use in pregnancy in their patient information leaflets. In addition, the regulation of THR is a remit of the MHRA and the Echinacea exposure from THR is therefore not considered in the combined consumption scenarios discussed below.

155. Pregnant women may use a combination of Echinacea containing foods such as tea, honey and lozenges in addition to food supplements in the form of tablets, capsules and oral liquids during pregnancy. The FSA's Exposure Team calculated consumption values for Echinacea during pregnancy, assuming different combinations of tea, honey, lozenges, tablets/capsules and oral liquids in order to cover different worst-case exposure scenarios. These combined consumption values displayed in Tables 8a-8c Annex B (acute consumption) and Tables 9a-9a Annex B (chronic consumption) are based on supplement dose recommendations for the food supplements and NDNS consumption data for the tea, honey and lozenges combined with information on their Echinacea content from the product ingredient listing. Tables 7a and 7b show the estimated minimum and maximum consumption levels of Echinacea for different numbers of Echinacea containing products consumed under the acute and chronic consumption scenarios respectively. It is apparent that the consumption level resulting from combined use of food products and food supplements may reach up to 13,000 mg Echinacea (as dried herb/root) for acute consumption and up to 11,000 mg for the chronic consumption scenario, especially if 3 or more Echinacea containing products are consumed together.

Table 7a: Estimated minimum and maximum acute consumption of *Echinacea* (as dried root/herb), based on number of products consumed per day, during pregnancy.

Number of Echinacea products consumed per day	Minimum estimated consumption <i>Echinacea</i> (mg/day)	Maximum estimated consumption <i>Echinacea</i> (mg/day)
2	60	9,600
3	460	13,000
4	1,100	13,000
5	1,900	13,000

*Rounded to 2 significant figures.

Table 7b: Estimated minimum and maximum chronic consumption of *Echinacea* (as dried root/herb), based on number of products consumed per day, during pregnancy.

Number of <i>Echinacea</i> products consumed per day	Minimum estimated consumption <i>Echinacea</i> (mg/day)	Maximum estimated consumption <i>Echinacea</i> (mg/day)
2	50	7,600
3	450	11,000
4	1,000	11,000
5	1,600	11,000

*Rounded to 2 significant figures.