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Volume 24 Some Pharmaceutical Drugs

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Last updated: 7 April 1998

DAPSONE

VOL.: 24 (1980) (p. 59)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Dapsone has been tested by oral administration in mice and rats, by intraperitoneal administration in mice and by prenatal and lifetime oral exposure in mice and rats. In three different studies in rats, high doses of dapsone induced mesenchymal tumours of the spleen in males (and of the peritoneum in two studies). An increased incidence of tumours of the thyroid was found in rats of both sexes in one study and in males in another study.

In mice, the experiment involving intraperitoneal administration of dapsone could not be evaluated. The other two experiments did not provide evidence of carcinogenicity.

Dapsone and its acetylated metabolites were not mutagenic to *Salmonella typhimurium*. Attention is drawn to the absence of studies on the teratogenicity of this compound.

5.2 Human data

Dapsone is used mainly in the treatment of leprosy.

Several cases of cancer have been reported in patients with dermatitis herpetiformis treated with dapsone. There was no evidence of an increased rate of cancer in patients with leprosy, many of whom would also have been treated with the drug.

5.3 Evaluation

There is *limited evidence* for the carcinogenicity of dapsone in experimental animals. The epidemiological data were insufficient. No evaluation of the carcinogenicity of dapsone to humans can be made.

For definition of the italicized terms, see [Preamble Evaluation](#).

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

DIHYDROXYMETHYLFURATRIZINE

VOL.: 24 (1980) (p. 77)

CAS No.: 794-93-4

Chem. Abstr. Name: Methanol, {[6-[2-(5-nitro-2-furanyl)ethenyl]-1,2,4-triazin-3-yl]imino}bis-

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Dihydroxymethylfuratrizine was tested alone in female rats by oral administration. Although a few tumours of the small intestine were observed in treated animals, there was no difference in overall tumour incidence as compared with controls. Panfuran-S, a commercial formulation which contains dihydroxymethylfuratrizine, was also tested in male mice and male rats by oral administration; it induced benign and malignant tumours of the forestomach and small intestine in animals of both species and of the oesophagus in mice.

Attention is drawn to the absence of studies on the teratogenicity of this compound.

5.2 Human data

Dihydroxymethylfuratrizine in the form of Panfuran-S has been used in the past for treatment of acute gastrointestinal infections.

No case reports or epidemiological studies were available to the Working Group.

5.3 Evaluation

There are insufficient data to evaluate the carcinogenicity of dihydroxymethylfuratrizine alone in experimental animals. There is *sufficient evidence* that Panfuran-S, a commercial formulation which contains dihydroxymethylfuratrizine and several other compounds, is carcinogenic in experimental animals.

Subsequent evaluation: Suppl. 7 (1987) (p. 62: Dihydroxymethylfuratrizine - **Group 3**) (p. 69: Panfuran-S (containing dihydroxymethylfuratrizine) - **Group 2B**)

For definition of terms, see [Preamble Evaluation](#).

Synonyms for Dihydroxymethylfuratrizine

- 3-Bis(hydroxymethyl)amino-6-(5-nitro-2-furylethenyl)-1,2,4-triazine
- Bis(hydroxymethyl)furatrizine
- Furatone
- Furatone-S
- {[6-2-(5-Nitro-2-furyl)vinyl]as-triazin-3-yl]-imino}dimethanol
- *N*-[6-(5-Nitrofurfurylidene)methyl]-1,2,4-triazin-3-yl]iminodimethanol
- Panfuran-S

HYDRALAZINE AND HYDRALAZINE HYDROCHLORIDE

VOL.: 24 (1980) (p. 85)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Hydralazine hydrochloride was tested in one experiment in mice by oral administration. A significant increase in the incidence of lung tumours was reported.

Hydralazine is mutagenic for *Salmonella typhimurium*. Attention is drawn to the absence of published studies on the teratogenicity of this compound.

5.2 Human data

Hydralazine is used in the long-term treatment of essential and early malignant hypertension.

Two studies have suggested an association between hydralazine and human cancer. One was confined to patients with and without hydralazine toxicity, and potential confounding factors were not controlled for. The other involved a small number of subjects exposed to hydralazine, and the possibility of selection bias could not be excluded.

5.3 Evaluation

The experimental data, while providing *limited evidence* for the carcinogenicity of hydralazine hydrochloride, were difficult to interpret due to certain aspects of experimental design and analysis. The epidemiological data were insufficient. In view of the extensive use of this drug, further studies should be undertaken.

For definition of the italicized terms, see [Preamble Evaluation](#).

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

METHOXSALEN

VOL.: 24 (1980) (p. 101)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Methoxsalen alone has not been tested by skin application and was inadequately tested in mice by oral and by intraperitoneal administration.

It was tested in combination with long-wave ultra-violet light in mice by oral and intraperitoneal administration and by skin application: it increased the incidence of epidermal and dermal tumours.

Methoxsalen, mainly in combination with long-wave ultra-violet light, but also in the dark, was mutagenic in a variety of prokaryotic and eukaryotic cells.

Attention is drawn to the absence of studies on the teratogenicity of this compound.

5.2 Human data

Methoxsalen is mainly used in combination with long-wave ultra-violet light in the treatment of vitiligo and severe psoriasis.

Methoxsalen and long-wave ultra-violet light together have been associated with haematopoietic neoplasms in two patients, with basal-cell skin cancer in another, and with squamous-cell skin cancer in a cohort study of patients with psoriasis. In the cohort study, increased surveillance of study subjects may have biased comparisons with the general population. However, a change in the ratio of squamous- to basal-cell tumours, the appearance of tumours in body areas not normally exposed to sunlight, and a change in tumour incidence within the cohort would support a causal interpretation. In none of these reports could the possible effects of methoxsalen alone be distinguished from those of long-wave ultra-violet light or of the combination of the two. Methoxsalen alone did not alter the incidence of skin cancer over two years in two small controlled trials of its use as a putative prophylactic for this disease.

These data are insufficient to allow a conclusion as to the carcinogenicity of methoxsalen in humans.

5.3 Evaluation

The available experimental and epidemiological data on methoxsalen alone were inadequate to make an evaluation of its carcinogenicity.

There is *sufficient evidence* that methoxsalen increases the carcinogenic effects of long-wave ultra-violet light in mouse skin. In view of the combined use of these agents in the treatment of skin disorders in humans, further studies should be undertaken of humans who have been exposed to them.

For definition of the italicized terms, see [Preamble Evaluation](#).

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

NAFENOPIN

VOL.: 24 (1980) (p. 125)

CAS No.: 3771-19-5

Chem. Abstr. Name: Propanoic acid, 2-methyl-2-[4-(1,2,3,4-tetrahydro-1-naphthalenyl)phenoxy]-

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Nafenopin was tested in acatalasemic mice (a strain with an unstable catalase gene) and in male rats by oral administration: it produced hepatocellular carcinomas in both species. A low incidence of pancreatic tumours was also observed in rats.

It was not mutagenic in *Salmonella typhimurium*.

5.2 Human data

Nafenopin has been suggested for use as a hypolipidaemic agent.

No case reports or epidemiological studies were available to the Working Group.

5.3 Evaluation

There is *sufficient evidence* for the carcinogenicity of nafenopin in experimental animals. For practical purposes, nafenopin should be regarded as if it presented a carcinogenic risk to humans.

Subsequent evaluation: Suppl. 7 (1987) (p. 67: **Group 2B**)

For definition of terms, see [Preamble Evaluation](#).

Synonyms for Nafenopin

- CH 13-437
- CIBA 13437 Su
- C 13437 Su
- Melipan
- 2-Methyl-2-[4-(1,2,3,4-tetrahydro-1-naphthalenyl)phenoxy]propanoic acid
- 2-Methyl-2-[*para*-(1,2,3,4-tetrahydro-1-naphthyl)phenoxy]propionic acid
- α -Methyl- α -(*para*-1,2,3,4-tetrahydronaphth-1-ylphenoxy) propionic acid
- Nafenoic acid
- Su 13437
- TPIA

PHENACETIN

VOL.: 24 (1980) (p. 135)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Phenacetin alone was tested in three studies in rats by oral administration and in combination with aspirin and caffeine in one study in mice and in one in rats by oral administration. In one study in rats, phenacetin alone induced benign and malignant tumours of the urinary tract and of the nasal cavity in males. When given in combination with aspirin and caffeine to rats or mice, no significant association was found between the administration of the mixture and the incidence of tumours. Phenacetin alone enhanced the urinary bladder carcinogenesis of *N*-nitrosobutyl-*N*-(4-hydroxybutyl)amine in rats.

Phenacetin is mutagenic to *Salmonella typhimurium* in the presence of a hamster liver microsome preparation, and it produces chromosome aberrations in Chinese hamster fibroblasts *in vitro*. No mutagenic effects were detected in *Drosophila melanogaster* or in mice *in vivo*, or in bacterial test systems when rat or mouse liver microsome preparations were used.

No teratogenic effects were found in rats, although embryotoxicity was observed.

N-Hydroxyphenacetin, a minor metabolite of phenacetin in humans, was tested by oral administration in male rats: it induced hepatocellular carcinomas.

N-Hydroxyphenacetin is mutagenic to *Salmonella typhimurium* in the presence of a rat liver microsome preparation.

5.2 Human data

Phenacetin is used extensively as a mild analgesic. Its use in certain countries has been restricted.

There are many case reports of renal pelvic cancer associated with abuse of analgesic mixtures containing phenacetin. In addition, an increased incidence of renal pelvic cancer has been reported in a population with a high prevalence of analgesic abuse; analgesic abuse has been reported to be more common in patients with renal pelvic cancer than in those with other urinary-tract neoplasms; and in one small follow-up study, renal pelvic cancer developed nine times more frequently in patients with analgesic nephropathy than in those with other chronic renal disease. One small case-control study showed no evidence of the association, although the prevalence of prior analgesic abuse was very low. Cases of other urinary-tract tumours have also been reported in association with analgesic abuse, but analytical studies have been inconclusive.

Two studies of pregnant women exposed to phenacetin alone or in combination with other drugs failed to find evidence of an increased rate of malformations in the offspring.

5.3 Evaluation

There is *limited evidence* that phenacetin and *N*-hydroxyphenacetin, a metabolite, are carcinogenic in experimental animals.

There is *limited evidence* that abuse of analgesic mixtures containing phenacetin causes cancer of the renal pelvis in humans. It is not possible to specify what component(s) of the analgesic mixtures may be responsible for this effect. There is insufficient evidence to link analgesic abuse with other tumours of the human urinary

tract.

For definition of the italicized terms, see [Preamble Evaluation](#).

Previous evaluation: [Vol. 13 \(1977\)](#)

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

Last updated: 7 April 1998

PHENAZOPYRIDINE AND PHENAZOPYRIDINE HYDROCHLORIDE

VOL.: 24 (1980) (p. 163)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Phenazopyridine hydrochloride was tested in mice and rats by oral administration and in mice by intraperitoneal administration. After its oral administration in female mice, it significantly increased the incidence of hepatocellular adenomas and carcinomas. In male and female rats, it induced tumours of the colon and rectum.

Attention is drawn to the absence of studies on the mutagenicity or teratogenicity of this compound.

5.2 Human data

Phenazopyridine hydrochloride is a weak urinary-tract analgesic and is possibly antiseptic.

In one epidemiological study, involving a limited period of observation, no association was observed between use of phenazopyridine hydrochloride and any cancer.

5.3 Evaluation

There is *sufficient evidence* for the carcinogenicity of phenazopyridine hydrochloride in experimental animals. The available epidemiological data are insufficient to evaluate the carcinogenicity of phenazopyridine hydrochloride to humans. In the absence of adequate data in humans, phenazopyridine hydrochloride should be regarded, for practical purposes, as if it presented a carcinogenic risk to humans.

For definition of the italicized terms, see [Preamble Evaluation](#).

Previous evaluation: [Vol. 8 \(1975\)](#)

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

PHENELZINE AND PHENELZINE SULPHATE

VOL.: 24 (1980) (p. 175)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Phenelzine sulphate was tested in mice by oral administration: it significantly increased the incidence of lung and blood vessel tumours in females.

Phenelzine sulphate is mutagenic in bacteria.

Phenelzine sulphate has been shown to be embryotoxic in mice.

5.2 Human data

Phenelzine sulphate is a monoamine oxidase inhibitor with limited use in the treatment of depressive states.

The single case report of angiosarcoma in a woman taking phenelzine sulphate provides insufficient evidence to assess the carcinogenicity of this compound in humans.

5.3 Evaluation

There is *limited evidence* that phenelzine sulphate is carcinogenic in experimental animals. In view of the evidence in experimental animals, the mutagenicity of phenelzine sulphate and a single case report of angiosarcoma of the liver in a patient taking phenelzine sulphate, further studies on the carcinogenicity of this compound are warranted.

For definition of the italicized terms, see [Preamble Evaluation](#).

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

PHENOXYBENZAMINE AND PHENOXYBENZAMINE HYDROCHLORIDE

VOL.: 24 (1980) (p. 185)

Phenoxybenzamine

CAS No.: 59-96-1

Chem. Abstr. Name: Benzenemethanamine, *N*-(2-chloroethyl)-*N*-(1-methyl-2-phenoxyethyl)-

Phenoxybenzamine hydrochloride

CAS No.: 63-92-3

Chem. Abstr. Name: Benzenemethanamine, *N*-(2-chloroethyl)-*N*-(1-methyl-2-phenoxyethyl)-, hydrochloride

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Phenoxybenzamine was tested intraperitoneally in mice; it produced an increased incidence of lung tumours.

Phenoxybenzamine hydrochloride was tested intraperitoneally in mice and rats; it produced local peritoneal sarcomas in animals of both sexes.

Attention is drawn to the absence of adequate studies on the mutagenicity or teratogenicity of phenoxybenzamine or its hydrochloride.

5.2 Human data

Phenoxybenzamine hydrochloride has limited use as an α -adrenergic receptor blocking agent.

No case reports or epidemiological studies were available to the Working Group.

5.3 Evaluation

There is *sufficient evidence* that phenoxybenzamine hydrochloride is carcinogenic in experimental animals by intraperitoneal administration. No data on humans were available.

Previous evaluation: [Vol. 9 \(1975\)](#)

Subsequent evaluation: Suppl. 7 (1987) (p. 70: Phenoxybenzamine hydrochloride - **Group 2B**)

For definition of terms, see [Preamble Evaluation](#).

Synonyms for Phenoxybenzamine

- Benslyte
- 2-*N*-Benzyl-2-chloroethylamino)-1-phenoxypropane
- Benzyl(2-chloroethyl)-(1-methyl-2-phenoxyethyl)amine
- *N*-Phenoxyisopropyl-*N*-benzyl- β -chloroethylamine

Synonyms for Phenoxybenzamine hydrochloride

- Bensylyt NEN
- 2-(*N*-Benzyl-2-chloroethylamino)-1-phenoxypropane hydrochloride
- Benzyl(2-chloroethyl) (1-methyl-2-phenoxyethyl)amine hydrochloride
- Benzylyt
- Blocadren
- Dibenylin
- Dibenyline
- Dibenzylene
- Dibenzylamine
- Dibenzylamine
- Dibenzylamine
- Fenoxylbenzamin
- Phenoxybenzamine HCl
- *N*-Phenoxyisopropyl-*N*-benzyl- β -chloroethylamine hydrochloride
- SKF 688A

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PROFLAVINE, PROFLAVINE DIHYDROCHLORIDE, PROFLAVINE HEMISULPHATE AND PROFLAVINE MONOHYDROCHLORIDE

VOL.: 24 (1980) (p. 195)

Proflavin

CAS No.: 92-62-6

Chem. Abstr. Name: 3,6-Acridinediamine

Proflavine dihydrochloride

CAS No.: 531-73-7

Chem. Abstr. Name: 3,6-Acridinediamine, dihydrochloride

Proflavine hemisulphate

CAS No.: 1811-28-5

Chem. Abstr. Name: 3,6-Acridinediamine, sulfate (2:1)

Proflavine monohydrochloride

CAS No.: 952-23-8

Chem. Abstr. Name: 3,6-Acridinediamine monohydrochloride

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Proflavine monohydrochloride, as the hemihydrate, was tested in mice and rats by oral administration. Proflavine hemisulphate was tested in mice by skin application, intradermal administration and subcutaneous implantation. All tests were inadequate for evaluation.

Proflavine is mutagenic in viral and bacterial systems. It increased the number of chromatid breaks and induced sister chromatid exchanges in mammalian cells.

Attention is drawn to the absence of studies on the teratogenicity of this compound.

5.2 Human data

Proflavine and its salts have limited use as topical disinfectants.

No case reports or epidemiological studies were available to the Working Group.

5.3 Evaluation

The available experimental results were *inadequate* for an evaluation of the carcinogenicity of proflavine in experimental animals, and no data were available from human studies. However, in view of its mutagenicity, confirmed in several experimental systems, further studies on the carcinogenicity of this compound are warranted.

Subsequent evaluation: Suppl. 7 (1987) (p. 70: Proflavine salts - **Group 3**)

For definition of italicized terms, see [Preamble Evaluation](#).

Synonyms for Proflavin

- 2,8-Diaminoacridinium
- 3,6-Diaminoacridinium
- 3,7-Diamino-5-aza-anthracene
- Isoflav base
- Proflavin
- Profoliol
- Profoliol-B
- Proformiphen
- Profundol
- Profura
- Progarmed
- Pro-Gen
- Progesic

Synonyms for Proflavine dihydrochloride

- 3,6-Diaminoacridine dihydrochloride
- 2,8-Diaminoacridinium chloride hydrochloride
- 3,6-Diaminoacridinium chloride hydrochloride
- Proflavin dihydrochloride

Synonyms for Proflavine hemisulphate

- 3,6-Acridinediamine sulphate
- 3,6-Diaminoacridine bisulphate
- 3,6-Diaminoacridine sulphate (1:1)
- 3,6-Diaminoacridinium monohydrogen sulphate
- 2,8-Diaminoacridinium sulphate
- Flavin sulphate
- Flavine
- Isoflav
- Neutral proflavine sulphate
- Pancridine
- Proflavin hemisulphate
- Proflavine sulphate
- Sanoflavin

Synonyms for Proflavine monohydrochloride

- 3,6-Diaminoacridine monohydrochloride
- 3,6-Diaminoacridinium chloride hydrochloride
- 2,8-Diaminoacridinium chloride monohydrochloride
- Proflavin monohydrochloride

RESERPINE

VOL.: 24 (1980) (p. 211)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Reserpine was tested in two experiments in mice by oral administration; in one experiment it induced malignant mammary tumours in females and carcinomas of the seminal vesicles in males. It was tested in three experiments in rats by oral administration; in one experiment it increased the incidence of pheochromocytomas in males. The other study in mice and the other two studies in rats were inadequate for evaluation.

Reserpine is embryotoxic and has effects on reproduction. There is limited evidence that it is teratogenic in experimental animals. It was not mutagenic in *Salmonella typhimurium*.

5.2 Human data

Reserpine is used mainly for the treatment of mild or moderate hypertension.

Thirteen case-control and two cohort studies on the relationship of reserpine to breast cancer were available to the Working Group. Between and within studies, estimates of relative risk for different measures of reserpine use varied from as low as 0.6 to over 3. Many of the positive findings were not coherent with one another; and the studies considered to be the most satisfactory, methodologically, showed little or no evidence of an increased risk.

Two studies of pregnant women receiving reserpine failed to find clear evidence of teratogenicity.

5.3 Evaluation

There is *limited evidence* that reserpine is carcinogenic in experimental animals.

The studies in humans are not consistent in showing an increase in risk of breast cancer associated with reserpine use; and, considering all studies together and the methodological problems of some, such an increase appears unlikely. Because of sampling variation, however, a small increase in risk (of the order of 50% or less) cannot be ruled out.

For definition of the italicized terms, see [Preamble Evaluation](#).

Previous evaluation: [Vol. 10 \(1976\)](#)

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

RIFAMPICIN

VOL.: 24 (1980) (p. 243)

CAS No.: 13292-46-1

Chem. Abstr. Name: Rifamycin, 3-[[[4-methyl-1-piperazinyl]imino]methyl]

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Rifampicin has been tested in two strains of mice and in rats by oral administration. It was also tested in mice by subcutaneous administration. After oral administration, it significantly increased the incidence of benign and malignant liver-cell tumours only in female mice of one strain; no evidence of carcinogenicity was observed in animals of the other strain. In rats, no increased tumour incidence was found. The experiment by subcutaneous administration was inadequate.

The available studies on mutagenicity indicated the absence of a mutagenic effect.

Rifampicin is teratogenic for mice and rats.

5.2 Human data

Rifampicin is a commonly used antimycobacterial drug. Its use in human medicine has increased recently.

No case reports or epidemiological studies were available to the Working Group.

In a preliminary report, nine malformations occurred among the children of 229 women exposed to the drug. (Three had defects of the central nervous system, and three had skeletal reduction defects.)

5.3 Evaluation

In view of the *limited evidence* for the carcinogenicity of rifampicin in mice and the absence of epidemiological studies, no evaluation of the carcinogenicity of rifampicin to humans could be made.

Subsequent evaluation: Suppl. 7 (1987) (p. 71: **Group 3**)

For definition of terms, see [Preamble Evaluation](#).

Synonyms

- Archidyn
- Arficin
- 5,6,9,17,19,21-Hexahydroxy-23-methoxy-2,4,12,16,18,20,22-heptamethyl-8-[N-(4-methyl-1-piperazinyl)formimidoyl]-2,7-[epoxypentadeca(1,11,13)trienimino]-naphtho(2,1-b)furan-1,11(2H)-dione-21-acetate
- 3-(4-Methylpiperazinyliminomethyl)-rifamycin SV
- 3-[[[4-Methyl-1-piperazinyl]imino]methyl rifamycin SV
- NSC113926
- R/AMP
- Rifa

- Rifaldazin
- Rifaldazine
- Rifadin
- Rifadine
- Rifagen
- Rifaldin
- Rifamate
- Rifampicin SV
- Rifampicinum
- Rifampin
- Rifamycin AMP
- Rifaprodin
- Rifinah
- Rifobac
- Rifoldin
- Rifoldine
- Riforal
- Rimactan
- Rimactane
- Rimactazid
- Rimactizid
- Tubocin

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SPIRONOLACTONE

VOL.: 24 (1980) (p. 259)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Spironolactone was tested by oral administration in two experiments in rats. An increased incidence of thyroid and testicular tumours was reported in one experiment but not in another experiment of longer duration with lower doses.

Attention is drawn to the absence of studies on the teratogenicity and mutagenicity of this compound.

5.2 Human data

Spironolactone is an aldosterone antagonist commonly used as a potassium-sparing diuretic.

Five cases of breast cancer were reported in women who had used a drug containing spironolactone. Four analytical studies, however, showed no consistent evidence of an association.

5.3 Evaluation

The experimental studies, while providing *limited evidence* of a carcinogenic effect, were difficult to interpret because of inadequacies and inconsistencies in reporting. Epidemiological studies have not confirmed the suspicion raised by case reports that spironolactone may cause breast cancer in humans. The data are insufficient, however, to permit confident exclusion of such an effect.

For definition of the italicized terms, see [Preamble Evaluation](#).

Subsequent evaluations: [Suppl. 7 \(1987\)](#); [Vol. 79 \(2001\)](#)

SULFAMURAZOLE

VOL.: 24 (1980) (p. 275)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Sulfamurazole was tested in mice and rats by oral administration: no increases in tumour incidences were observed.

No adequate studies of mutagenicity were available.

It is teratogenic for mice and rats.

5.2 Human data

Sulfamurazole is one of the most commonly used sulfonamide drugs in the treatment of urinary tract infections. Its production has remained stable during recent years.

In one hypothesis-seeking epidemiological study, no association was observed between sulfamurazole use and any cancer.

In two large studies of women exposed during pregnancy, no increase in malformation rate was observed in the offspring.

5.3 Evaluation

The data from studies in experimental animals and in humans were not indicative of a carcinogenic effect but were not sufficient for an evaluation of the carcinogenicity of sulfamurazole to humans.

Subsequent evaluation: [Suppl. 7 \(1987\)](#)

SULFAMETHOXAZOLE

VOL.: 24 (1980) (p. 285)

5. Summary of Data Reported and Evaluation

5.1 Experimental data

Sulfamethoxazole was tested in one experiment in rats by oral administration: it produced thyroid tumours.

No mutagenic effects were observed. Attention is drawn to the absence of studies on the teratogenicity of this compound.

5.2 Human data

Sulfamethoxazole is commonly used in the treatment of urinary-tract infections.

In one hypothesis-seeking epidemiological study, an association between sulfamethoxazole use and nasopharyngeal and cervical cancers was noted.

5.3 Evaluation

There is *limited evidence* for the carcinogenicity of sulfamethoxazole in experimental animals. The epidemiological data were insufficient. No evaluation of the carcinogenicity of sulfamethoxazole to humans could be made.

For definition of the italicized terms, see [Preamble Evaluation](#).

Subsequent evaluation: [Suppl. 7 \(1987\)](#); [Vol. 79 \(2001\)](#)

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