

Case Series Drug Analysis Print

Name: Repevax FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 30-Sep-2004
MedDRA Version: MedDRA 24.0

Repevax FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the Repevax Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	3	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	3	0
Tachycardia	1	0
Cardiac disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Lens disorders congenital</i>		
Cataract congenital	3	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Syndactyly	1	0
Congenital disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
Ear disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
Strabismus	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Eye disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	10	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Odynophagia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	13	0
Vomiting	34	0
<i>Oral soft tissue disorders NEC</i>		
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral discomfort	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
Gastrointestinal disorders SOC TOTAL	73	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
Administration site rash	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site exfoliation	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	1	0
Fatigue	8	0
Malaise	18	0
<i>Febrile disorders</i>		
Pyrexia	64	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
Feeling cold	1	0
Feeling drunk	1	0
Feeling hot	38	0
Thirst	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crepitations	1	0
Crying	4	0
Discharge	1	0
Illness	2	0
Induration	10	0
Influenza like illness	1	0
Local reaction	98	0
Peripheral swelling	170	0
Screaming	2	0
Swelling	83	0
Swelling face	4	0
<i>Inflammations</i>		
Inflammation	61	0
<i>Injection site reactions</i>		
Injection site bruising	3	0
Injection site dermatitis	1	0
Injection site discolouration	5	0
Injection site discomfort	2	0
Injection site erythema	80	0
Injection site induration	15	0
Injection site inflammation	45	0
Injection site irritation	3	0
Injection site joint warmth	1	0
Injection site mass	9	0
Injection site oedema	1	0
Injection site pain	28	0
Injection site pruritus	11	0
Injection site rash	6	0
Injection site reaction	45	0
Injection site swelling	72	0
Injection site urticaria	1	0
Injection site vesicles	10	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site warmth	20	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Oedema NEC		
Localised oedema	1	0
Oedema	2	0
Oedema peripheral	5	0
Pain and discomfort NEC		
Chest discomfort	1	0
Chest pain	2	0
Discomfort	3	0
Pain	22	0
Tenderness	9	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	4	0
Vaccination site bruising	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	1	0
Vaccination site discomfort	2	0
Vaccination site erythema	63	0
Vaccination site induration	2	0
Vaccination site inflammation	7	0
Vaccination site irritation	1	0
Vaccination site joint erythema	2	0
Vaccination site joint inflammation	1	0
Vaccination site joint swelling	1	0
Vaccination site mass	6	0
Vaccination site pain	17	0
Vaccination site pruritus	1	0
Vaccination site rash	7	0
Vaccination site reaction	8	0
Vaccination site swelling	52	0
Vaccination site vesicles	3	0
Vaccination site warmth	29	0
General disorders SOC TOTAL	1194	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	1	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	17	0
Type IV hypersensitivity reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
Immune system disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Administration site cellulitis	5	0
Application site cellulitis	1	0
Cellulitis	52	0
Injection site cellulitis	8	0
Vaccination site cellulitis	14	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Corynebacteria infections</i>		
Diphtheria	1	0
<i>Ear infections</i>		
Ear infection	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Infections NEC</i>		
Infection	4	0
Injection site infection	2	0
Vaccination site infection	3	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	2	1
<i>Skin structures and soft tissue infections</i>		
Rash pustular	1	0
Skin infection	1	0
<i>Tuberculous infections</i>		
Erythema induratum	4	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Rhinitis	1	0
Tonsillitis	2	0
Upper respiratory tract infection	1	0
Infections SOC TOTAL	113	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	15	0
Foetal exposure during pregnancy	10	0
Maternal exposure during pregnancy	6	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
Medication error	3	0
Wrong technique in product usage process	3	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	1	0
Wound dehiscence	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Expired product administered	4	0
Inappropriate schedule of product administration	5	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	6	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	2	0
<i>Skin injuries NEC</i>		
Contusion	9	0
Scar	1	0
Skin abrasion	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
Injuries SOC TOTAL	73	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal monitoring abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	3	0
Heart rate irregular	2	0
Radial pulse abnormal	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Liver function test abnormal	1	0
<i>Metabolism tests NEC</i>		
Urine ketone body present	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	6	0
Respiratory rate decreased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Urinalysis NEC</i>		
Protein urine present	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
<i>White blood cell analyses</i>		
White blood cell count increased	1	0
Investigations SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	10	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia neonatal	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	6	0
Joint effusion	1	0
Joint stiffness	2	0
Joint swelling	1	0
<i>Muscle infections and inflammations</i>		
Myositis	3	0
<i>Muscle pains</i>		
Myalgia	5	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	3	0
Muscle swelling	1	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Floppy infant	1	0
Muscle rigidity	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	3	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	4	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	2	0
Pain in extremity	33	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	1	0
Muscle & tissue disorders SOC TOTAL	80	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	1	0
Acute polyneuropathies		
Guillain-Barre syndrome	2	0
Coordination and balance disturbances		
Coordination abnormal	1	0
Hand-eye coordination impaired	1	0
Cortical dysfunction NEC		
Dyspraxia	1	0
Disturbances in consciousness NEC		
Depressed level of consciousness	1	0
Lethargy	2	0
Loss of consciousness	5	0
Somnolence	9	0
Syncope	20	0
Dyskinesias and movement disorders NEC		
Dyskinesia	3	0
Hypokinesia	1	0
Movement disorder	1	0
Psychomotor hyperactivity	1	0
Dystonias		
Opisthotonus	1	0
Encephalitis NEC		
Encephalitis post immunisation	1	0
Facial cranial nerve disorders		
Bell's palsy	1	0
Facial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	2	0
Headaches NEC		
Headache	13	0
Tension headache	1	0
Migraine headaches		
Migraine	1	0
Muscle tone abnormal		
Hypotonia	12	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurological signs and symptoms NEC		
Dizziness	10	0
Head discomfort	1	0
Presyncope	3	0
Unresponsive to stimuli	7	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	2	0
Paraesthesias and dysaesthesias		
Hypoaesthesia	1	0
Paraesthesia	2	0
Seizures and seizure disorders NEC		
Epilepsy	1	0
Febrile convulsion	1	0

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Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myoclonic epilepsy	1	0
Neonatal seizure	1	0
Partial seizures	1	0
Seizure	4	0
Seizure like phenomena	1	0
<i>Sensory abnormalities NEC</i>		
Allodynia	1	0
Sensory disturbance	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	1	0
<i>Tremor (excl congenital)</i>		
Tremor	4	0
Nervous system disorders SOC TOTAL	128	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
Foetal hypokinesia	8	0
<i>Foetal position and presentation abnormalities</i>		
Breech presentation	2	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	2	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	5	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal placental thrombosis	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	3	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	2
Stillbirth	7	7
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	39	9

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
Staring	3	0
<i>Anxiety symptoms</i>		
Anxiety	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Emotional distress	1	0
Irritability	4	0
Mood altered	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
Hallucination, visual	1	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	4	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
Psychiatric disorders SOC TOTAL	31	0

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Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	3	0
Urinary retention	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Renal failure and impairment</i>		
Renal impairment	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Renal structural abnormalities and trauma</i>		
Pyelocaliectasis	1	0
Renal & urinary disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	5	0
Reproductive & breast disorders SOC TOTAL	6	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	6	0
Respiration abnormal	1	0
Respiratory depression	1	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	2	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	14	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
Nasal pruritus	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	4	0
Rhinorrhoea	1	0
Snoring	1	0
Respiratory disorders SOC TOTAL	36	0

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Skin disorders		
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	7	0
Hyperhidrosis	2	0
Bullous conditions		
Blister	26	0
Dermatitis bullous	1	0
Erythema multiforme	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Papule	1	0
Skin discolouration	3	0
Skin induration	2	0
Skin lesion	3	0
Skin reaction	10	0
Skin texture abnormal	1	0
Skin warm	15	0
Dermatitis and eczema		
Dermatitis	2	0
Dermatitis allergic	3	0
Eczema	4	0
Skin irritation	3	0
Erythemas		
Erythema	217	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	0
Pruritus NEC		
Pruritus	39	0
Rashes, eruptions and exanthems NEC		
Rash	19	0
Rash erythematous	6	0
Rash macular	2	0
Rash maculo-papular	1	0
Rash morbilliform	1	0
Rash pruritic	6	0
Skin vascular conditions NEC		
Skin oedema	1	0
Urticarias		
Urticaria	22	0
Skin disorders SOC TOTAL	403	0

Case Series Drug Analysis Print

Name: Repevax FOI 21/1063

Report Run Date: 07-Oct-2021

Data Lock Date: 30-Sep-2021 18:30:04

Earliest Reaction Date: 30-Sep-2004

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	1	0
Social circumstances SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: Repevax FOI 21/1063

Report Run Date: 07-Oct-2021

Data Lock Date: 30-Sep-2021 18:30:04

Earliest Reaction Date: 30-Sep-2004

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	5	0
Vacuum extractor delivery	1	0
Surgical & medical procedures SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: Repevax FOI 21/1063

Report Run Date: 07-Oct-2021
Earliest Reaction Date: 30-Sep-2004

Data Lock Date: 30-Sep-2021 18:30:04
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Non-site specific vascular disorders NEC</i>		
Hyperaemia	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	9	0
Flushing	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	24	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	46	0
TOTAL REACTIONS FOR DRUG	2333	10
TOTAL REPORTS	1008	
TOTAL FATAL OUTCOME REPORTS		10